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Fax-on-Demand
Telephone: 202-401-0527
Item: xxxx

104PP

Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals

EPA ICR No.: 1188.07

OMB Control No. 2070-0038

1(b) Short Characterization

Section 5 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2604 (Attachment 1), authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import or process the substance for that use. Regulations implementing significant new uses appear at 40 CFR part 721 (Attachment 2).

Once EPA receives a significant new use rule (SNUR) notice, EPA may take regulatory action under TSCA sections 5(e), 5(f), 6 or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the Federal Register its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Section 5(a)(2) of TSCA provides OPPT with the authority to monitor and control significant new uses of existing chemical substances. The factors considered by the Administrator in determining a significant new use are:

1) The projected volume of manufacturing and processing of a chemical substance;
2) The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;

CONTAIN NO CBI

3) The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and

4) The reasonably anticipated manner and methods of manufacturing, ,processing, distribution in commerce, and disposal of a chemical substance.

Once the Administrator makes such a designation, the Agency proposes a Significant New Use Rule (SNUR). If a final rule is promulgated, a person who intends to engage in a significant new use of a chemical covered by a SNUR must notify EPA of his/her intentions. This notification, made via the Significant New Use Notice **(SNUN),** must occur at least 90 days prior to commencing the new use of the identified substance. The required notice must be submitted on EPA's Premanufacture Notice (PMN) form. The PMN form provides data on the identity and use of, and possible exposures to, the chemical substance. In addition, the PMN form provides test data plus descriptions of health and environmental effects data based on the manufacture, processing, use, 'distribution in commerce, and disposal of the chemical.

The Agency has 90 days to evaluate a SNUN once it has been received. This evaluation focuses on the health and environmental effects of the substance's significant new use. Should EPA find cause for concern, the Agency can take regulatory action as per TSCA sections 5(e) and 5(f)[1]. Likewise, the Agency may extend the evaluation period by up to 90 days with good cause. If EPA takes no action at the end of the review period, the submitter can engage in the intended new use without any restrictions.

2(b) Use/Users of the Data

EPA uses this information to evaluate the health and environmental effects of the significant new use. During the evaluation period EPA can take further regulatory action pursuant to TSCA sections 5(e) and 5(f). Under TSCA section 5(e), the Administrator may issue an order to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of such substance. TSCA section 5(f) allows the Administrator to, among other things, prohibit or limit the manufacture of the chemical substance, if the substance presents or will present an unreasonable risk of injury to health or the environment.

To date EPA has promulgated SNURs on 74 existing chemicals. Presented in Attachment 6 are selected case history abstracts for some of these substances. These abstracts highlight the needs of a particular office and the facts surrounding a substance. This information when applied to the Regulatory Selection Criteria has resulted in final SNURs.

'Section 5(e) allows the Administrator to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or **disposal of the substance when the substance *may* present an unreasonable risk. TSCA section 5(f) allows the Administrator to use a TSCA section 6 regulation to prohibit or limit the manufacture of the substance when the substance *will* present an unreasonable risk.**

3. NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

EPA is the only Federal Agency that collects information on significant new uses of chemical substances. A notification of an intent to engage in a significant new use serves two functions: as a notice, and **as** a document that contains information about a chemical substance and potential exposures to that substance. The notification element is unique to SNURs and therefore not obtainable elsewhere. The chemical information aspect will also contain unique information. Only the person who intends to commence a significant new use of a chemical substance will know the potential for human and environmental exposures to that substance, the quantity intended to be produced, imported, or processed, and the manner in which the person will engage in the significant new use.

A .person submitting a significant new use notice is not required to develop test data. However, the person must submit data that are known to or reasonably ascertainable by that person. For published data the submitter need only provide a literature citation (40 CFR 720.50(d)(3)(ii)). For existing chemicals that are related to the chemical substance that is the subject of the SNUR (e.g., impurities, byproducts), neither the published data nor a literature citation need be submitted. Also, notices need not include information previously submitted to EPA (unless the previously submitted information was claimed confidential, in which case it must be resubmitted).

3(b) Public Notice Required Prior to ICR Submission to OMB

Prior to submission to OMB, this ICR will be made available to the public for comment through a Federal Register notice. The public will have **60** days to provide comments. Any comments received will be given consideration when completing the supporting statement that is submitted to OMB.

3(c) Consultations

EPA received comments in response to several individual proposed SNURs. All comments were considered in developing the final rules. It is EPA policy to consider all comments received in response to proposed SNURs.

3(d) Effects of Less Frequent Collection

Whenever a person intends to engage in a significant new use, they must notify EPA. This is an explicit requirement of TSCA. Section 5(a)(1)(B) of TSCA states "no person may manufacture or process any chemical substance for a use which the Administrator has determined **...** is a significant new use **...** unless such person submits to the Administrator **...** a notice ..." The consequence of less frequent collection of information (i.e., requiring only the first person who intends to engage in a significant new use to submit notice) is a violation of TSCA and would allow

manufacturers, importers and processors to use a substance in a manner that EPA has determined may cause significant adverse exposures to the substance without prior notification to EPA.

3(e) General Guidelines

This information collection activity is necessary to implement the statutory requirements of TSCA section 5(a)(2) and is consistent with the requirements of *5* CFR **1320.6.**

3(f) Confidentiality

Information provided in a significant new use notice may receive confidential treatment. TSCA section 14 allows a manufacturer, importer or processor to designate submitted information as confidential business information (CBI). The Agency has developed a comprehensive system to prevent the unauthorized disclosure of CBI. This system includes procedures for logging CBI in and out of designated locked file cabinets, for photocopying and transmitting CBI, and for restricting confidential information only to personnel with CBI security clearance. No one is allowed access to CBI until they have received instructions for handling CBI.

Special procedures also restrict access to computerized CBI. These security measures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. A wrongful disclosure of CBI may result in either a fine or imprisonment.

3(g) Sensitive Questions

This section is not applicable. The information requested is not sensitive in nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents SIC Codes

TSCA section 5(a)(2) rule covers predominantly those firms in SIC code major groups 28 - "Chemicals and Allied Products," and code 2911 - "Petroleum Refining."

4(b) Information Requested

(i) Respondent Activities and Data Items

Only those persons who intend to engage in a significant new use of a chemical substance must submit notice of their intentions to EPA. Submitters are required to use the Premanufacture Notice form (PMN; see Attachment **3),** which was developed to facilitate the information collection process for new chemical substances. The notice must include, insofar as it is known to or reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (i.e.,

chemical identity, use, and exposure data), as well as test data, and descriptions of other data related to the effects on health and the environment of the manufacture, processing, use, distribution in commerce, and disposal of the chemical substance (TSCA section 5(d)). After a notice has been received, EPA has 90 days (extendable to 180 days) to evaluate the notice's content.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

A significant new use rule (SNUR) on an existing chemical substance is the product of a process that is designed to develop the appropriate information-gathering collection for a substance. This process has three major steps: Chemical Referral, Regulatory Selection, and Regulation Development.

Step 1. **Chemical Referral:** EPA offices that have identified information-gathering or follow-up monitoring needs for a particular chemical may refer the substance to the Office of Pollution Prevention and Toxics (OPPT). A systematic process has been developed for receiving and handling chemical referrals. Offices referring substances are asked to prepare concise summaries of relevant data. This information is used to select a regulatory approach and for rulemaking activities.

Step 2. **The Regulatory Selection Process - Referral and Review:** Once an office has detailed its need for information, an information collection approach is determined that best satisfies that office's needs. The rulemaking options are: a TSCA section 8(a) reporting rule, a TSCA section 8(c) call-in, a TSCA section 8(d) health and safety data reporting rule, a TSCA section 5(a)(2) SNUR, or any combination of the above. It may also be determined that an alternative approach is more appropriate (e.g., use of existing data sources, no data-gathering at the present time, TSCA section 4 or 6 action, or referral to another office for information-gathering under a different statutory authority).

Step 3. **Regulatory Development:** Prior to the development of a rule, the recommended rulemaking approach must be reviewed by the referring office and approved by the Office Director of OPPT. If the recommendation is approved, then the rulemaking process begins.

A SNUR is drafted only if it is an appropriate approach for a particular substance that has received approval prior to the development of the rule. The proposal then undergoes intra-agency review, OMB review and public comment. Once a decision has been made to promulgate an information collection rule, the next decision is to determine whether a TSCA section 8(a) rule or a TSCA section 5 SNUR is most appropriate. Attachment 5 identifies the selection criteria that are applied in determining whether a TSCA section 8(a) rule or SNUR is proposed.

5(b) Collection Methodology and Management

EPA has not been able to identify a more efficient, less expensive or more flexible means of obtaining the required data and remain within the constraints of TSCA. There is no new technology applicable to the collection of this information that would minimize the collection burden.

To aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA section 5(a)(2) reporting as well as other regulatory information. When Hotline staff are unable to answer questions regarding TSCA section 5(a)(2), the questions are referred to the OPPT Chemical Control Division (CCD) staff for resolution.

5(c) Small Entity Flexibility

All business, regardless of size, must comply with the requirements of TSCA section 5. However, OPPT has taken a number of steps intended to minimize the burden placed on small business. For instance, TSCA section 26(d) established an Assistance Office to provide technical and other nonfinancial assistance to manufacturers, importers and processors of chemical substances and mixtures. This office has established a toll-free hotline, performs on-site field visits and consultations, and has hired a contractor to assist small businesses, free of charge, in complying with TSCA requirements.

5(d) Collection Schedule

Whenever any person intends to engage in a significant new use of a chemical substance, they are required to submit a notice of their intentions to EPA not less than 90 days before beginning to manufacture, import or process the substance for the intended use.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

This section presents estimates of the cost and burden associated with the recordkeeping and reporting requirements of TSCA section 5(a)(2). The methodology used to estimate the recordkeeping costs, reporting costs, and burden for this ICR renewal is largely based on previous experience with SNURs, and is largely consistent with the analysis presented in the supporting statement prepared for the previous ICR. **A** *summary* of the steps employed in this analysis is shown below:

Step 1: The total number of SNURs promulgated and SNUNs to be submitted, on an annual basis and for the three-year period during which this ICR will be in effect, was projected. The estimate is based on the Agency's experience with SNURs and SNUR reporting since 1985.

Step 2: The average industry burden associated with recordkeeping, reporting, and customer notification was estimated. The reporting burden estimates used here are taken from an analysis performed in connection with OPPT's amendments to its premanufacture notification (PMN) program.

Step 3: The unit costs for the different activities associated with section 5(a)(2) were estimated next (e.g., filing a SNUN). The costs were derived by multiplying current estimates of unit labor costs by the burden estimates presented in Step 2.

Step 4: Total industry costs and burden were computed by multiplying the average burden and cost per activity by the expected number of activities.

Step 5: The final step estimates the cost to EPA. These estimates are taken from the previous version of the ICR and updated to **1998** dollars.

6(a) Estimating Respondent Burden

Based on previous experience, EPA assumes the following regarding the number of SNURs and SNUNs that will be issued over the three-year period for the ICR:

1) EPA will promulgate **3** SNURs per year, for a total of **9** rules over **3** years.
2) EPA will receive ***5*** **SNUNs** each year, for a total of 15 notices over **3** years.

These estimates are summarized in Table 1.

EPA believes that these estimates provide a reasonable representation of regulatory activities for the three-year period covered by this ICR, and thus has incorporated them into this analysis.

TABLE 1
ANTICIPATED NUMBER OF SNURs AND SNUNs

Year	Anticipated Number of SNURs	Anticipated Number of SNUNS
First Year	**3**	***5***
Second Year	**3**	5
Third Year	**3**	***5***
Three-Year Totals	**9**	**15**

Source: Alwood, *2001*.

Given the uncertainty in projecting possible new uses for existing chemicals, it is not possible to determine if a large or small number of firms would be affected by any given **SNUR,** or whether any one firm might engage in more than one new use. Thus, this analysis makes the assumption that no firm submits more than one **SNUN.** The total number of firms engaging in new uses cannot be estimated.

Under current regulations at 40 **CFR** 721.5(a)(2), all manufacturers, processors and importers of chemicals subject to **SNURs** will also be affected, regardless of whether such entities engage in a significant new use[2]. However, without prior knowledge of chemicals that would be the subject of future **SNURs,** estimating the number of potentially affected entities subject to 40 **CFR** 721.5(a)(2) is not possible.

1. Alternative Responses

The burden associated with a **SNUR** could involve a number of possible industry responses. That is, when a **SNUR** is promulgated, a firm seeking to engage in a new use for a subject chemical has **5** options regarding possible courses of action:

a.) The company could submit a **SNUN.** This option would be chosen by any company not intending to abide by the provisions of the **SNUR.**

b.) **A** company can request an equivalency determination. This option would be chosen if a manufacturer/importer had reason to believe that there may be alternative methods not considered by EPA that provide equivalent or superior protection from exposure or release of the subject chemical.

c.) The company can comply with the **SNUR,** ensuring that all provisions of the **SNUR** are implemented in connection with the planned use of the subject chemical.

d.) The company can request review of the **SNUR** for possible modification or revocation.

e.) The company may simply decide to forgo the new use, avoiding regulatory compliance activities altogether.

The following section estimates the cost of submitting a **SNUN** (option 1) and then discusses the other options.

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[2]Unless **manufacturers, processors and importers of chemicals subject to SNURs have either notified recipients** of **such chemicals and all significant new uses, verified that knowledge of the SNUR has been otherwise acquired by recipients, or verified that recipients are unable to engage in significant new uses, manufacturers, processors and importers must file a SNUN.**

2. Burden Estimates

TSCA section 5(a)(2) imposes two requirements on industry. First, manufacturers, processors and importers of chemicals must choose among the options mentioned above. This section presents estimates of submitting SNUNs (i.e., the first option) and then briefly discusses the other four options. Second, manufacturers, processors and importers of chemicals covered by SNURs will incur burden and costs to notify customers of the hazards posed by the covered chemical.

Submitting a SNUN

In submitting a SNUN, individuals at different occupational levels must spend time on the required recordkeeping and reporting activities. In estimating the burden required to prepare a SNUN, the analysis uses the breakdown of activities and activity estimates as developed for the premanufacture notification (PMN) baseline model in the Agency's "Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications'' (OPPT, **1994).** The PMN reporting cost estimates were used because SNUNs would be filed on the standard PMN form. Table 2 presents EPA's estimate of respondent reporting burden associated with the filing of a SNUN.[3]

[3]**The burden estimates presented in Table 2 differ from the PMN Amendments analysis, which were based on a Chemical Manufacturers Association survey, only in that burden for researching synonyms and generic chemical names was not included in this analysis. This is because subject chemicals would be existing chemicals, and such information would already be known.**

TABLE 2
UNIT REPORTING BURDEN ESTIMATES ASSOCIATED WITH FILING A SNUN, BY LABOR CATEGORY

Activity	Secretarial Hours	Technical Hours	Managerial Hours	Total Hours
General information/ instructions	2-2.5	1.5-2	3 - 4	6.5 - 8.5
Chemical identity	1.5 - 2	3 - 6	1	5.5-9
Trade name ID		.25		.25
Byproducts/impurities identification		1		1
Production & marketing data	1.5		2 - 3	3.5-4.5
Production volume		1		1
Category of use		3		3
Hazard information		3 - 4		3 - 4
Human exposure and environmental release	2.5 - 3.5		6 - 7	8.5-10.5
Site information		14-16		14-16
Occupational exposure		13-14		13-14
Environmental release/ disposal		9-10		9-10
Sites controlled by others	2	10-12	2 -2.5	14- 16.5
List of attachments	2	6 - 8	1 - 1.5	9 - 11.5
Certification			.5	.5
Data submissions	.5	1.5-2	.5	2.5-3
Totals	**12 - 14**	**66.25 - 79.25**	**16 - 20**	**94.25 - '113.25**

Source: OPPT, 1994.

In keeping with the conservative assumptions already employed, the high end of the range of reporting burden hours (i.e., 113.25 hours) will be used in subsequent cost calculations. The recordkeeping associated with preparing and filing a SNUN is assumed to require 5 percent of the time spent onreporting. Thus, 5.67 record keeping hours ([113.25 hours] * [5 percent]) will be spent in preparation of a SNUN. The average industry burden per notice, then, is 118.92 hours (113.25 + 5.67).

The estimates shown in Table 2 are average burden levels. Thus, it is entirely possible that certain respondents may incur burden above or below the estimates shown above; nevertheless, EPA believes the upper bound of the range of average burden hours to be an appropriate estimate for the calculations performed in this analysis.

Alternative Options

Should a company choose to request an equivalency determination (i.e., the second option), or review for modificatiodrevocation (i.e., the fourth option), EPA estimates that a data collection and preparation effort similarto that of a SNUN would be required, and thus the burden is estimated to range up to 118.92 hours for these alternatives, the same as for submitting a **SNUN.**

In complying with a SNUR, a company would incur costs to ensure all provisions of the SNUR were implemented at the subject facility (i.e., the third option). Since the nature of such provisions will vary depending on the significant new uses identified in each respective SNUR, estimating burden at this time is not possible.

The final alternative for a company considering a significant new use of a chemical that is the subject of a SNUR is to forgo the new use (i.e., the fifth option). In carrying out such a response, no direct regulatory burden, or costs, would be incurred.

Customer Notification

In addition to the burden of submitting a SNUN, manufacturer, processors and importers will incur a burden associated with notifying customers. As noted above, all manufacturers, processors and importers of chemicals subject to SNURs will be affected. Since it is not expected that all such entities will have complete knowledge of all uses of any products subject to a SNUR, and because filing a SNUN could require significantly more burden, it is assumed that manufacturers, processors and importers will most often choose to notify their customers of SNUR regulatory activities. As this notification may be accomplished by simply annotating an **MSDS,** EPA estimates the associated burden to be about 1 hour of a technical employee's time per manufacturer, processor, or importer. Therefore, the average industry burden per SNUR would equal 119.92 hours (118.92 hours for SNUN preparation plus 1 hour for customer notification).

6(b) Estimating Respondent Costs

The unit costs of filing a SNUN are estimated by monetizing the labor time spent preparing the SNUN and then adding any fixed costs associated with filing a SNUN. This section derives these unit costs.

1. Wages

The basic methodology for estimating the industry wage rates used in this analysis was developed for the Comprehensive Assessment Information Rule (CAIR) (USEPA, 1995). This is the same methodology used in the previous ICR, with some refinements.

The hourly wage rates used in this analysis are derived in Appendix **A** of this report. Wage data used to develop the basic industry wage rates are derived from the **U.S.** Department of Labor, Bureau of Labor Statistics (BLS) for all goods-producing private industries. The annual salary estimates were adjusted to second-quarter (June) 2001 dollars using the BLS Employment Cost Index (ECI) for white-collar occupations for all private industries.

An overhead rate of **17** percent was applied to all wages based on information provided by the chemical industry and chemical industry trade associations. Benefit rates were applied to wages as follows: managerial, 40.5 percent; technical, 41.6 percent; and secretarial, 43.4 percent. Thus, total load factors are 58 percent for managerial labor, 59 percent for technical labor, and **60** percent for secretarial labor. The current (June 2001) hourly wage and load rates (overhead and benefits) are presented in Table 3. Details on the calculation of the wage rates can be found in Attachment 4.

TABLE 3
HOURLY WAGE AND LOAD RATES FOR INDUSTRY

Labor Category	June 2001	2001 Load Rates
Managerial	$98.34	58%
Technical	$72.89	59%
Secretarial	$29.39	***60%***

Note: Details on the calculation of these wages can be **found** in Appendix A. Sources: **BLS, 1998;** 2001a,b.

2. Summary of Unit Costs

Labor Costs

Using these labor wage rates and the burden estimates presented above, EPA estimates that the labor cost associated with filing a **SNUN** ranges from $6,755 to $8,155. These costs are

estimated by multiplying the wage rate for each labor category by the number of hours for each labor category from Table 3. Thus, the lower bound **($6,755)** is estimated as: **[$98.34** (managerial labor)] * **[16** hours] + **[$72.89** (technical labor)] * **[66.25** hours] + **[$29.39** (clerical labor)] * **[12** hours]). The upper bound **($8,155)** is estimated as: **[$98.34** (managerial labor)] * **[20** hours] + **[$72.89** (technical labor)] * **[79.25** hours] + **[$29.39** (clerical labor)] * **[14** hours]). In addition, **SNUN** filers must pay a **$2,500** user fee. Thus, the total cost of filing a SNUN ranges from **$9,255** to **$10,655.**

Alternative Responses

As noted in Section **4,** firms planning to engage in significant new uses of subject chemicals could choose five alternative responses to any particular SNUR. Although EPA has not projected or quantified how frequently these alternatives might be selected, the unit costs associated with each option are discussed briefly below.

The estimated burden of requesting an equivalency determination (the second option) or review for modificatiodrevocation (the fourth option) was judged to be similar to filing the **SNUN;** thus, total costs including the EPA user fee were estimated to range from between **$9,255** and **$10,655.** However, the firm may incur additional costs in developing the data necessary to justify the alternative. This option will be preferable to compliance with the SNUR if the total cost of obtaining EPA approval of a request is less than the costs of SNUR compliance.

SNUR compliance costs are likely to be dominated by capital outlays and/or worker training, and could vary widely depending upon the significant new use in question and the characteristics of the affected facility.

Finally, if the cost of controlling exposures is too great to justify the production, importation, or processing of the SNUR-listed substance, a company may forgo the new use. While this decision incurs no direct costs, it does mean that the firm may lose benefits that might have been gained from the chemical. These lost potential benefits cannot be quantified because EPA cannot anticipate the future use levels of these chemicals, the profit margins of these uses, and so on.

Customer Notification

EPA assumes that the customer notification requirement will be handled by technical labor. This analysis assumed that one hour of labor per chemical would be required to perform the notification. Thus the unit cost of notification is estimated to be **$72.89** (i.e., the hourly wage for technical labor).

Summary

Table **4** summarizes the unit costs estimated in this section. Filing a **SNUN** is estimated to cost between **$9,255** and **$10,655** per SNUN and notifying customers is estimated to cost **$64.30** per chemical. As noted above, the upper bound cost for filing a SNUN **($10,655)** will be used in subsequent calculations.

TABLE 4
SUMMARY OF UNIT COSTS

Unit Cost	Estimated Cost
Filing a SNUN	Between $9,255 and $10,655 per SNUN
Notifying Customers	$72.89 per chemical

6(c) Agency Burden and Costs

EPA will incur costs associated with the promulgation of SNURs and the processing of SNUNs. The previous ICR estimated that the cost for issuing a SNUR can be as high as $29,400 in 1998 dollars. The Office of Personnel Management reports that federal salaries increased by 12.95 percent between 1998 and 2001 (Office of Personnel Management, 2001)[4]. Thus, inflating the 1998 estimate to 2001 yields an estimate of $33,207 per SNUR ($29,400 * [1.012951). This is the cost of 3.94 person-months of EPA staff time required to develop a final SNUR[5]. In addition, in the previous ICR EPA estimated that is would spend $11,861 to process each SNUN[6]. Using the 12.95 percent increase in federal salaries, the 2001 'cost is estimated to be $13,397 ($11,861 * [1.12951).

Using the estimates of annual SNUR promulgation and SNUR notice submissions presented above, EPA's estimated costs are presented in Table 5. Promulgating SNURs and processing SNUNs are estimated to cost the Agency $166,606 annually, and $499,818 for three years. The Agency may also incur a cost for modifying a SNUR if submitted data indicate a need for such an action. Costs to perform such a modification have not been estimated.

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[4]This percentage increase is composed of three annual increases: a 3.68 percent increase in 1999, a 4.94 percent increase in 2000, and a 3.81 percent increase in 2001 (Office of Personnel Management, 2001). The percentage increase from 1995 to 1998 is calculated by the product of each annual markup (i.e., 1.0368 * 1.0494 * 1.0381).

[5]The 3.94 person-months estimate is from a memorandum from Michael Shapiro, Economics and Technology Division, to Susan Hazen, Office of Toxic Substances (Shapiro, 1984). The cost is based on the Shapiro methodology and updated to current wage rates. That is, a GS-13/1 employee earned $51,557/year in 1995. Adding 60% for overhead and benefits yields a wage of $82,491/year. Dividing this wage by 12 person-months/year results in $6,874/person-month. Multiplied by 3.94 person-months/SNUR, this yields an EPA costs per SNUR of $27,084 in 1995 dollars. These estimates were inflated to 1998 dollars in the previous ICR. This ICR inflates the salaries to 2001 dollars using the 12.95 percent increase in federal salaries from 1998 to 2001 (Office of Personnel Management, 2001).

[6]This estimate is based on the analysis of 1983 PMN reporting form, adjusted up to the 1995 federal pay rate (an estimated increase of 11.5%) (RIB, 1983).

TABLE 5
AGENCY COSTS

Activity	Number Per Year	Cost Per Action	Annual Cost	Three-Year Cost
SNURs	3	$33,207	$99,621	$298,863
SNUNs	5	$13,391	$66,985	$200,955
Totals	**8**	**$46,604**	**$166,606**	**$499,818**

Note: Estimates may contain some rounding error caused by rounding dollar values to the nearest whole dollar.

6(d) Total Burden and Costs to Industry

This section provides estimates of the total burden and costs imposed by the TSCA section 5(a) requirements. They are divided into two categories: submitting SNUNs and notifying customers.

1. Submitting: SNUNs

The total cost and burden imposed on industry by TSCA section 5(a)(2) requirements can be calculated by multiplying the unit burden and cost estimates by the expected number of SNURs and SNUNs. As noted above, this analysis assumes that EPA will promulgate three SNURs and receive five SNUNs per year.

Table 6 presents the total burden of submitting SNUNs. This analysis estimated that the reporting requirements for submitting SNUNs would impose 113.25 hours for each SNUN. An additional 5.67 hours are assumed to be required to satisfy recordkeeping requirements. Thus, a total of 118.92 hours is required for each SNUN[7]. EPA estimates that it will receive five SNUNs per year. Thus, the total burden imposed on industry is estimated to be 594.6 hours annually, or 1,783.8 hours over a three-year period.

[7] In deriving the totals for this analysis, EPA uses the upper bound estimates for the number of hours and the cost of submitting SNUNs.

TABLE 6
TOTAL INDUSTRY BURDEN ASSOCIATED WITH SUBMITTING SNUNs

Activity	Hours Per SNUN	SNUNs per Year	Total hours
Reporting	113.25	5	566.25
Recordkeeping	5.67	5	28.35
Total Annual Burden	**118.92**	**5**	**594.6**
Three-Year Burden	-	-	**1,783.8**

The total cost of submitting SNUNs is presented in Table 7. This analysis estimated that submitting SNUNs will cost affected parties $10,655 per SNUN. Assuming 5 SNUNs per year implies a total annual cost of $53,275 ([5 SNUNs] * [$10,655 per **SNUN])** and a three-year cost of $159,825 ([$53,275 per year] * [3 years]).

TABLE 7
TOTAL INDUSTRY COSTS ASSOCIATED WITH SUBMITTING SNUNs

SNUNs Per Year	Cost Per SNUN	Total Annual Cost	Three-Year Cost
5	$10,655	$53,275	$159,825

Note: ,Estimates may contain some rounding error caused by rounding dollar values **to** the nearest whole dollar.

2. Customer Notification

Table 8 presents estimates of the customer notification burden and costs. EPA estimates that each SNUR will cover approximately 65.5 chemicals (Alwood, 2001)[8]. EPA also assumes that each manufacturer, processor or importer will require one hour to comply with the customer notification requirement and that there are two manufacturers, processors or importers per chemical'. This analysis assumed that **3** SNURs would be issued annually. Thus, the total annual burden is calculated as the product of these elements, or 393 hours ([65.5 chemicals per SNUR] * [1 hour per

[8]This estimate is based on data provided by Jim Alwood, EPA/OPPT/CCD, to Lynne Blake-Hedges, EPA/OPPT/EPAB, September 17,2001 (Alwood, 2001). The estimate was calculated by taking the number of chemicals covered under non-section 5(e) SNURs between **1998** and 2001. This number (262) was then divided by the annual average number **of** non- section 5(e) **SNURs** (4), to get the average number of chemicals per **SNUR** (65.5). This estimate was then assumed to apply to the TSCA section 5(a) **SNURs** covered by this ICR.

'The second assumption, two manufacturers, processors or importers per chemical, follows from previous ICRs for these requirements.

manufacturer, processor, or importer] * [2 manufacturers, processors or importers per chemical] * [3 SNURs per year]). The three-year burden is 1,179 hours.

The cost of customer notification is estimated by multiplying the burden hours by the unit cost of notification. This analysis assumed that notification would be accomplished using technical labor, valued at $72.89 per hour. Thus, the total annual cost of customer notification is $28,646 and the three-year cost is $85,938

TABLE 8
ESTIMATED BURDEN AND COST FOR CUSTOMER NOTIFICATION

Cost element	Value/Estimate
Burden	
Chemicals per SNUR	65.5
Hours per manufacturer/processor/importer	1.0
Manufacturers/processors/importers per chemical	2
SNURs per year	
Total annual burden hours (65.5 * 1.0 * 2 * 3)	393
Three-year burden hours (3 * 393)	1,179
cost	
Cost per hour	$72.89
Total annual cost (393 hours * $72.89)	$28,646
Three-year cost ($28,646 * 3)	$85,938

3. Summary of Industry Costs

The total estimated industry burden associated with SNURs is equal to the total reporting and record keeping burden (594.6 hours annually) plus the total customer notification burden (393 hours annually) which is equal to 987.6 hours annually. The associated cost is estimated to be $53,275 (total annual reporting and record keeping cost) plus $28,646 (total annual customer notification cost), or $81,921 annually. Over a three-year period, the burden is estimated to be 2,963 hours and costs are estimated to be $245,763.

6(e) Reasons for Change in Burden

Since the last clearance, annual industry burden estimates have decreased from 1,032 hours to 988 hours. This change results from updating estimates based upon historical information on SNURs promulgated by the EPA (adjustment). Based upon revised estimates, the number of SNUNs estimated to be received annually has increased from 3 to 5. Additionally, the estimated number of chemicals per SNUR has increased from 34 to 65.5. However, the estimated annual number of SNURs has decreased from 10 to 3 based upon historical information. This results in a decrease in notification burden. The overall result of these adjustments is a decrease in estimated burden.

6(f) Regulatory Flexibility

TSCA section 5(a)(c) affects new uses of chemicals and requires those interested in engaging in such a use to notify the Agency of his/her intentions. Because the rule only covers uses that a small business intends to undertake, a small business is not expected to immediately be affected by the SNUR unless it is considering such a use in the future. Although there may be some small businesses that may decide to participate in SNUR-related activities associated with certain chemicals, it is impossible to estimate the number at this time. Additionally, the Agency has only received over 20 SNUNs related to existing chemical SNURs to date, suggesting that few, if any, small business would be affected. This, coupled with the low unit costs associated with filing a SNUN, suggests that the overall impact will be low for any business that may choose to file a SNUN or notify customers of SNUR activity. These costs are not differentiated between small and large businesses.

6(g) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0038, is estimated to be 118.9 hours per response. According to the Paperwork reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. In addition, the OMB control numbers for EPA's regulation, after initial display in the final rule, are listed in 40 CFR part 9.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through

the use of automated collection techniques, to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (Mail Code 2822), 1200 Pennsylvania Ave., NW., Washington, D.C. 20460. Include the OMB control number identified above in any correspondence. Do not submit the completed form or requested information to this address. The actual information or form should be submitted in accordance with the instructions accompanying the form, or as specified in the corresponding regulations.

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ATTACHMENT 1

Toxic Substances Control Act Section 5

Laws in effect as of January **2,2001**

TITLE 15--COMMERCE AND TRADE

CHAPTER 53--TOXIC SUBSTANCES CONTROL

SUBCHAPTER I--CONTROL OF TOXIC SUBSTANCES

Sec. **2604.** Manufacturing and processing notices

(a) In general

(1) Except **as** provided in subsection (h) of this section, no person may--

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section **2607(b)** of this title, or

(B) manufacture or process any chemical substance for a use which the Administrator has determined; in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d) of this section, of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection **(b)** of this section.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including--

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) Submission of test data

(1)(A) If (i) a person is required by subsection (a)(1) of this section to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section **2603** of this title before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1) of this section.

(B) If--

(i) a person is required by subsection (a)(**1**) of this section to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule promulgated under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) of this section or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B) of this section.

(2)(A) If a person–

(i) is required by subsection (a)(1) of this section to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule promulgated under section 2603 of this title before the submission of such notice to submit test data for such substance,

such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1) of this section.

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that--

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A) of this section, the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B) of this section, the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including–

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(11) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under

subsection (a)(2) of this section, would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

(c) Extension of notice period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) of this section before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) of this section shall include--

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) of this section or of data under subsection (b) of this section, the Administrator shall publish in the Federal Register a notice which--

(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b) of this section, describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection

(b) of this section or a rule under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance

by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) of this section and for which the notification period prescribed by subsection (a), (b), or (c) of this section has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) of this section; and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c) of this section, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph **(A)** respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c) of this section, and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a) of this section, the Administrator makes the determination described in paragraph (1)(A) and if--

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(11) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it, the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the

United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) of this section; and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) of this section to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 2605(a) of this title respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) Protection against unreasonable risks

(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a) of this section, or that any combination of such activities,

presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 2605 of this title can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) of this section to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(2)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may--

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) of this section to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 of this title can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities.

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) of this section shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) of this section shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C) of this section, the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

(g) Statement of reasons for not taking action

If the Administrator has not initiated any action under this section or section 2605 or 2606 of this title to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b) of this section, before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) of this section to permit such person to manufacture or process a chemical substance for test marketing purposes--

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) of this section to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that--

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for he Administrator as required by subsection (b)(2) of this section, and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) of this section for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules f the Administrator)--

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under

subsection (b)(2) of this section to .submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period–

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending--

(I) five years after the date referred to in clause (i), or

(11) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data, whichever is later.

(3) The requirements of subsections (a) and (b) of this section do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of--

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any **risk** to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and **(3)** of section 2605(c) of this title.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) of this section inapplicable with respect to the manufacturing or processing of any chemical substance **(A)** which exists temporarily as a result of a chemical reaction in the manufacturing or

processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph **(1)** or *(5)* the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within **45** days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) ''Manufacture''and ''process''defined

For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(Pub. L. **94-469,** title I, Sec. **5**, Oct. **11, 1976, 90** Stat. **2012;** renumbered title I, Pub. L. **99-519,** Sec. 3(c)(1), Oct. **22, 1986, 100** Stat. **2989.)**

ATTACHMENT 2

40 CFR Part 721 (Subpart A through Subpart D)

This data current as of the Federal Register dated March 14,2002

40 CFR PART 721

SUBPART A - GENERAL PROVISIONS

§ 721.1 Scope and applicability.

(a) This part identifies uses of chemical substances, except for microorganisms regulated under part 725 of this chapter, which EPA has determined are significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act. In addition, it specifies procedures for manufacturers, importers, and processors to report on those significant new uses. This subpart A contains general provisions applicable to this part. subpart B of this part identifies generic requirements for certain significant new uses cross referenced in specific provisions of subpart E of this part. subpart C of this part identifies generic reporting requirements for certain significant new uses cross referenced in specific provisions of subpart E of this part. subpart E of this part identifies chemical substances and their significant new uses.

(b) This subpart A contains provisions governing submission and review of notices for the chemical substances and significant new uses identified in subpart E of this part. The provisions of this subpart A apply to the chemical substances and significant new uses identified in subpart E of this part, except to the extent that they are specifically modified or supplanted by specific requirements in subpart E of this part. In the event of a conflict between the provisions of this subpart A and the provisions of subpart E of this part, the provisions of subpart E of this part shall govern.

(c) The provisions of part **720** of this chapter apply to this part 721. For purposes of this part 721, wherever the phrase "new chemical substance" appears in part 720 of this chapter, it shall mean the chemical substance subject to this part 721. In the event of a conflict between the provisions of part 720 of this chapter and the provisions of this part 721, the provisions of this part 721 shall govern.

[53 FR 28358, July 27,1988, as amended at 62 FR 17932, Apr. 11,19971

§ 721.3 Definitions.

The definitions in section 3 of the Act, 15 U.S.C. 2602, and § 720.3 of this chapter apply to this part. In addition, the following definitions apply to this part:

Acutely toxic effects A chemical substance produces acutely toxic effects if it kills within a short time period (usually 14 days):

(1) At least 50 percent of the exposed mammalian test animals following oral administration of a single dose of the test substance at 25 milligrams or less per kilogram of body weight (LD50).

(2) At least 50 percent of the exposed mammalian test animals following dermal administration of a single dose of the test substance at 50 milligrams or less per kilogram of body weight (LD50).

(3) At least 50 percent of the exposed mammalian test animals following administration of the test substance for **8** hours or less by continuous inhalation at a steady concentration in air at 0.5 milligrams or less per liter of air (LC50).

CAS Number means Chemical Abstracts Service Registry Number assigned to a chemical substance on the Inventory.

Chemical name means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

Chemical protective clothing means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

Commercial use means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment **or** painting contractor).

Common name means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

Consumer means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

Consumer product means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence; in or around a school, or in recreation.

Customer means any person to whom a manufacturer, importer, or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

Director of the Office of Pollution Prevention and Toxics means the Director of the EPA Office **of**
Pollution Prevention and Toxics or any EPA employee delegated by the Office Director to carry out the Office Director's functions under this part.

Employer means any manufacturer, importer, processor, or user of chemical substances or mixtures.

Environmentally transformed A chemical substance is "environmentally transformed" when its chemical structure changes as a result of the action of environmental processes on it.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person).

Identity means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

Immediate use A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

Impervious Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

Manufacturing stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

Metalworking fluid means a liquid of any viscosity or color containing intentionally added water and used in metal machining operations for the purpose of cooling, lubricating, or rust inhibition.

MSDS means material safety data sheet, the written listing of data for the chemical substance as required under § 721.72(c).

NIOSH means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

Non-enclosed process means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

Non-industrial use means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

Personal protective equipment means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons,

hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

Powder or dry solid form means a state where all or part of the substance would have the potential to become fine, loose, solid particles.

Principal importer means the first importer who, knowing that a chemical substance will be imported for a significant new use rather than manufactured in the United States, specifies the chemical substance and the amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

Process for commercial purposes means the preparation of a chemical substance or mixture containing the chemical substance, after manufacture of the substance, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture containing the chemical substance is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, the impurities also are processed for commercial purposes.

Process solely for export means to process for commercial purposes solely for export from the United States under the following restrictions on activity in the United States: Processing must be performed at sites under the control of the processor; distribution in commerce is limited to purposes of export; and the processor may not use the chemical substance except in small quantities solely for research and development.

Process stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

Recipient means any person who purchases or otherwise obtains a chemical substance directly from a person who manufacturers, imports, or processes the substance.

Serious acute effects means human injury or human disease processes that have a short latency period for development, result from short-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Serious chronic effects means human injury or human disease processes that have a long latency period for development, result from long-term exposure to a chemical substance, or are a combination of these factors and which are likely to result in death or severe or prolonged incapacitation.

Short-term test indicative of carcinogenic potential means either any limited bioassay that measures tumor or preneoplastic induction, or any test indicative of interaction of a chemical substance with **DNA** (i.e., positive response in assays for gene mutation, chromosomal aberrations, **DNA** damage and repair, or cellular transformation).

Short-term test indicative of the potential to cause a developmentally toxic effect means either any in vivo preliminary development toxicity screen conducted in a mammalian species, or any in vitro developmental toxicity screen, including any test system other than the intact pregnant mammal, that has been extensively evaluated and judged reliable for its ability to predict the potential to cause developmentally toxic effects in intact systems across a broad range of chemicals or within a class of chemicals that includes the substance of concern.

Significant adverse environmental effects means injury to the environment by a chemical substance which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or which may adversely affect a threatened or endangered species. A substance will be considered to have the potential for significant adverse environmental effects if it has one of the following:

(1) An acute aquatic EC50 of 1 mg/L or less,

(2) An acute aquatic EC50 of 20 mg/L or less where the ratio of aquatic vertebrate 24-hour to 48-hour EC50 is greater than or equal to 2.0.

(3) A Maximum Acceptable Toxicant Concentration (MATC) of less than or equal to 100 parts per billion (100 ppb).

(4) An acute aquatic EC50 of 20 mg/L or less coupled with either a measured bioconcentration factor (BCF) equal to or greater than 1,000x or in the absence of bioconcentration data a log P value equal to or greater than 4.3.

Site means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

Site-limited intermediate means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

Spray application means any method of projecting a jet of vapor of finely divided liquid onto a surface to be coated; whether by compressed air, hydraulic pressure, electrostatic forces, or other methods of generating a spray.

Use stream means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

Waters of the United States has the meaning set forth in 40 CFR 122.2.

Work area means a room or defined space in a workplace where a chemical substance is manufactured, processed, or used and where employees are present.

Workplace means an establishment at one geographic location containing one or more work areas.

[53 FR 28358, July 27, 1988, as amended at 54 FR 31306, July 27, 1989; 58 FR 63516, Dec. 1, 1993]

§ 721.5 Persons who must report.

(a) The following persons must submit a significant new use notice as specified under the provisions of section 5(a)(1)(B) of the Act, part 720 of this chapter, and § 721.25:

(1) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to engage in a significant new use of the substance identified in that section.

(2) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in subpart E of this part, and intends to distribute the substance in commerce. A person described in this paragraph is not required to submit a significant new use notice if that person can document one or more of the following as to each recipient of the substance from that person:

(i) That the person has notified the recipient, in writing, of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(ii) That the recipient has knowledge of the specific section in subpart E of this part which identifies the substance and its designated significant new uses.

(iii) That the recipient cannot undertake any significant new use described in the specific section in subpart E of this part.

(b) A person described in paragraph (a)(2) of this section must submit a significant new use notice if that person has knowledge at the time of commercial distribution of the substance identified in the specific section in subpart E of this part that a recipient intends to engage in a designated significant new use of that substance without submitting a notice under this part.

(c) A person who processes a chemical substance identified in a specific section in subpart E of this part for a significant new use of that substance is not required to submit a significant new use notice if that person can document each of the following:

(1) That the person does not know the specific chemical identity of the chemical substance being processed.

(2) That the person is processing the chemical substance without knowledge that the substance is identified in subpart E of this part.

(d)(1) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in subpart E of this part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a significant new use notice.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart E of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC, 20044.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a notice under this part, the manufacturer, importer, or processor shall immediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a significant new use notice under this part and the notice review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in a significant new use without submitting a notice under this part, the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at 'the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.

(ii) The recipient has submitted a significant new **use** notice under this part and the notice review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

[53 FR 28359, July 27,1988, as amended at 60 FR 34464, July 3,19951

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name is subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to manufacture, import, or process the chemical substance for commercial purposes.

(b) To establish a bona fide intent to manufacture?import, or process a chemical substance, the person who intends to manufacture, import, or process the chemical substance must submit the following information in writing to the Document Control Office (7407), Office of Pollution Prevention and Toxics, **U.S.** Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: SNUR Bonafide submissions.

(1) The specific chemical identity of the chemical substance that the person intends to manufacture, import, or process.

(2) A signed statement that the person intends to manufacture, import, or process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture?import, or process the chemical substance.

(4) An elemental analysis.

(5) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or, if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(c) If an importer or processor cannot provide all the information required in paragraph (b) of this section because it is claimed as confidential business information **by** the importer's or processor's manufacturer or supplier, the manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under paragraph (b) of this section to determine whether than person has shown a bona fide intent to

manufacture, import, or process the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under § 710.7(e)(2)(v) of this chapter or the information requested under § 720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer, importer, or processor has shown a bona fide intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer, importer, or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

(f) A disclosure to a person with a bona fide intent to manufacture, import, or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

[53 FR 28359, July 27,1988, as amended at 60 FR 34464, July 3,19951

§ 721.20 Exports and imports.

Persons who intend to export a chemical substance identified in subpart E of this part, or in any proposed rule which would amend subpart E of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who import a substance identified in a specific section in subpart E of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR part 707.

[53FR 28360, July 27, 19881

§ 721.25 Notice requirements and procedures.

(a) Each person who is required to submit a significant new use notice under this part must submit the notice at least 90 calendar days before commencing manufacture, import, or processing of a chemical substance identified in subpart E of this part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on EPA Form 7710-25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

(b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in subpart E of this part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the

certification section of part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.

(c) EPA will process the notice in accordance with the procedures of part **720** of this chapter, expect to the extent they are inconsistent with this part **721.**

(d) Any person submitting a significant new use notice in response to the requirements of this part **721** shall not manufacture, import, or process a chemical substance identified in subpart E of this part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

[53 FR 28360, July **27,1988,** as amended at **60 FR 16311,** Mar. **29,19951**

§ **721.30** EPA approval of alternative control measures.

(a) In certain sections of subpart E of this part, significant new uses for the identified substances are described **as** the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of substances which are identified in such sections, or alternative measures to control worker exposure or environmental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) A request for a determination of equivalency must be submitted in writing to the Document Control Office **(7407),** Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, **Room G-099, 1200** Pennsylvania Ave., NW., Washington, DC **20460;** ATTN: **SNUR** Equivalency Determination, and must contain:

(1) The name of the submitter.

(2) The specific chemical identity of the substance.

(3) The citation for the specific section in subpart E of this part which pertains to the substance for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) An analysis justifying why such alternative control measures provide substantially the same

degree of protection as the specific control measures identified in the specific section in subpart E of this part 'which pertains to the substance for which the request is being submitted.

(7) The data and information described in § 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Pollution Prevention and Toxics, EPA.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, Office of Pollution Prevention and Toxics, or designee. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that EPA has determined that the alternative control measures provide substantially the same degree of protection as the specified control measures identified in the specified section of subpart E of this part which pertains to the substance for which the request is being submitted, the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this part.

[53 FR 28360, July 27,1988, as amended at 60 FR 34464, July 3,19951

§ 721.35 Compliance and enforcement.

(a) Failure to comply with any provision of this part is a violation of section 15(1) of the Act (15 U.S.C. 2614).

(b) Using for commercial purposes a chemical substance which a person knew or had reason to know was manufactured, imported, or processed in violation of this part is a violation of section 15(2) of the Act (15 U.S.C. 2614).

(c) Failure or refusal to permit access to or copying of records, as required by section 11 of the Act, is a violation of section 15(3) of the Act (15 U.S.C. 2614).

(d) Failure or refusal to permit entry or inspection, as required by section 11 of the Act, is a violation of section 15(4) of the Act.

(e) Violators of the Act or of this part may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. The submission of false or misleading information in connection with the requirement of any provision of this part may subject persons to penalties calculated as if they never filed a notice.

(f) Under the authority of sections 7 and 17 of the Act, EPA may:

(1) Seek to enjoin the manufacture, import, or processing of a chemical substance in violation of 'this part.

(2) Act to seize any chemical substance which is being manufactured, imported, or processed in yiolation of this part.

(3) Take any other appropriate action.

[53 FR 28361, July 27, 1988]

§ 721.40 Recordkeeping.

Any person subject to the requirements of this part must retain documentation of information contained in that person's significant new use notice. This documentation must be maintained for a period of 5 years from the date of the submission of the significant new use notice.

[53 FR 28361, July 27, 1988]

$721.45 Exemptions.

The persons identified in § 721.5 are not subject to the notification requirements of § 721.25 for a chemical substance identified in subpart E of this part, unless otherwise specified in a specific section in subpart E, if:

(a) The person has applied for and has been granted an exemption for test marketing the substance for a significant new use identified in subpart E of this part in accordance with section 5(h)(1) of the Act and § 720.38 of this chapter.

(b) The person manufactures, imports, or processes the substance for a significant new use identified in subpart E of this part in small quantities solely for research and development in accordance with § 721.47.

(c) The person has applied for and been granted an exemption under section 5(h)(5) of the Act.

(d) The person manufactures, imports, or processes the substance only as an impurity.

(e) The person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it **as** a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.

(f) The person imports or processes the substance as part of an article.

(g) The person manufactures or processes the substance solely for export and, when distributing the substance in commerce, labels the substance in accordance with section 12(a)(1)(B) of the

Act.

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance fiom EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§ 721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, $721.5 applies and § 721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

(i) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart E of this part, abiding by the provision of the section 5(e) order exempts the person fiom submitting a significant new use notice for that specific significant new use.

[53 FR 28361, July 27, 1988]

§ 721.47 Conditions for research and development exemption.

(a) A person who manufactures, imports, or processes a chemical substance identifies in subpart E of this part for a significant new use identified in subpart E of this part is not subject to the notification requirements of § 721.25 if the following conditions are met:

(1) The person manufactures, imports, or processes the substance for the significant new use in small quantities solely for research and development.

(2) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the chemicals substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under section 4, 5, or *6* of the Act that applies to the substance and of which the manufacturer, importer, or processor has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph (b)(2), a laboratory is defined as a contained research facility where relatively small quantities of chemical substances are used on a pro-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual).

(c)(1) The manufacturer, importer, or processor must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer, importer, or processor distributes a chemical substance manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(d) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, State, and local regulations, to the extent the disposal activity is not identified as a significant new use for the substance in subpart E of this part, or

(2) Used for a commercial purpose, to the extent the use is not identified as a significant new use of the substance in subpart E of this part.

(e)(1) Persons who manufacture, import, or process a chemical substance under this section must retain the following records:

(i) Copies of or citations to information reviewed and evaluated under paragraph (b)(1) of this section to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under paragraph (c)(1) of this section including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under paragraph (b)(2) of this section.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of the notifications required under paragraph (c)(2) of this section.

(2) [Reserved]

[53 FR 28361, July 27,1988, as amended at 58 FR 34204, June 23,19931

SUBPART B - CERTAIN SIGNIFICANTNEW USES

§ 721.50 Applicability.

This subpart B identifies certain significant new uses of chemical substances identified in subpart E of this part. The provisions of this subpart B apply only when referenced as applying to a chemical substance identified in subpart E of this part.

§ 721.63 Protection in the workplace.

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is any manner or method of manufacturing, importing, or

processing associated with any use of the substance without establishing a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the chemical substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 1910.133.

(2) In addition to any other personal protective equipment selected in paragraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs, and torso. Clothing provided under this paragraph need not be tested or evaluated under the requirements of paragraph (a)(3) of this section.

(3) The employer is able to demonstrate that each item of chemical protective clothing, including gloves, selected provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH-approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with *29* CFR 1910.134 and 30 CFR part 11.

(5) The following NIOSH approved respirators meet the minimum requirements for paragraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet or tight-fitting facepiece.

(iv) Category 21C air-purifying respirator equipped with a full'facepiece and high efficiency particulate filters.

(v) Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.

(vi) Category **2** 1C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

(vii) Category 21C air-purifying respirator equipped with a high efficiency particulate filter including disposable respirators.

(viii) Category **23C** air-purifying respirator equipped with a full facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(ix) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(x) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xi) Category 23C air-purifying respirator equipped with combination cartridges approved for paints, lacquers, and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xii) Category 23C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges.

(xiii) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges.

(xiv) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and organic gas/vapor cartridges.

(xv) Category 23C air-purifying respirator equipped with organic gas/vapor cartridges, including disposable respirators.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance apply to paragraphs (a) (1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Fume.

(iv) Smoke.

(v) Vapor.

(vi) Gas.

(b) If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(c)(1) If at any time after commencing distribution in commerce of a chemical substance that is identified in subpart E of this part as subject to this section, the person has knowledge that a recipient of the substance is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, the person is considered to have knowledge that the recipient is engaging in a significant new use and is required to follow the procedures in § 721.5(d) unless the person is able to document the following:

(i) That the person has notified the recipient in writing within 15 working days of the time the person first has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, and that the person has knowledge of the failure of implementation.

(ii) That within 15 working days of notifying the recipient that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section the person has received from the recipient, in writing, a statement of assurance that the recipient has established the program required under paragraph (a) of this section, and will take appropriate measures to avoid activities that are inconsistent with implementation of the

program required under paragraph (a) of this section.

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in § 721.5(d).

§ 721.72 Hazard communication program.

Whenever a substance is identified in subpart E of this part as being subject to this section, **a** significant new use of that substance is any manner or method of manufacture, import, or processing associated with any use of that substance without establishing a hazard communication program as described in this section.

(a) Written hazard communication program. Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, **MSDSs,** and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate **MSDS** for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

(2) The methods the employer will use to inform employees of the hazards of non-routine tasks involving the substance, for example, the cleaning of reactor vessels, and the hazards associated with the substance contained in unlabeled pipes in their work area.

(3) The methods the employer will use to inform contractors of the presence of the substance in the employer's workplace and of the provisions of this part applicable to the substance if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the substance while in the employer's workplace.

(b) Labeling. (1) Each employer shall ensure that each container of the substance in the workplace is labeled in accordance with this paragraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of health hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

(B) The identity by which the substance may be commonly recognized.

(C) A statement of environmental hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

(D) A statement of exposure and precautionary measure(s), if any, identified in subpart E of this part or by the employer.

(ii) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by paragraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The employer need not label portable containers into which the substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The employer shall not remove or deface an existing label on incoming containers of the substance unless the container is immediately relabeled with the information specified in paragraph (b)(1)(i) of this section.

(2) Each employer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this paragraph.

(i) The label shall, at a minimum, contain the following information:

(A) The information required under paragraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 **U.S.C.** 1801 et. seq.) and regulations issued under that Act by the Department **of** Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance

identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the employer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph.

(c) Material safety data sheets. (1) Each employer must obtain or develop a MSDS for the substance.

(2) Each MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the substance under this section, and, if not claimed confidential, the chemical and common name of the substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the employer (such as vapor pressure, flash point).

(iii) The physical hazards of the substance known to the employer, including the potential for fire, explosion, and'reactivity.

(iv) The potential human and environmental hazards as specified in subpart E of this part for the substance.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the substance known to the employer.

(vi) The primary routes of exposure to the substance.

(vii) Precautionary measures to control worker exposure and/or environmental release identified in subpart E of this part for the substance, or alternative control measures which EPA has determined under § 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the substance which are known to the employer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the employer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the employer.

(xi) The date of preparation of the **MSDS** or of its last revision.

(xii) The name, address, and telephone number of the individual preparing or distributing the **MSDS,** or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the **MSDS,** the employer must mark the **MSDS** to indicate that no applicable information was found.

(4) Where multiple mixtures containing the substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the employer may prepare one **MSDS** to apply to all of these multiple mixtures.

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new,information must be added to the **MSDS** within **3** months fiom the time the employer becomes aware of the new information. If the substance is not currently being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to the **MSDS** before the substance is reintroduced into the workplace.

(6) The employer must ensure that persons receiving the substance from the employer are provided an appropriate **MSDS** with their initial shipment and with the first shipment after an **MSDS** is revised. The employer may either provide the **MSDS** with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The employer must maintain a copy of the **MSDS** in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The **MSDS** may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for each substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The **MSDS** must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. Each employer must ensure that employees are provided with information and training on the substance identified in subpart E of this part. This information and training must be provided at the time of each employee's initial assignment to a work area containing the substance and whenever the substance subject to this section is introduced into the employee's work area for the first time.

(1) Information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances identified in subpart E of this part as subject to this section, and MSDSs required by paragraph (c) of this section.

(2) Training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the substance in or from an employee's work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the substance as specified in subpart E of this part.

(iii) The measures employees can take to protect themselves and the environment from the substance, including specific procedures the employer has implemented to protect employees and the environment from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under subpart E of the part, or alternative control measures which **EPA** has determined under § **72**1.30 provide substantially the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the employer under this section, including **an** explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low concentrations in mixtures. If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(f) Existing hazard communication program. The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health, environmental hazard, exposure, and precautionary statements. Whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section and the MSDS as specified in paragraph (c) of this

section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(1) Human health hazard statements: This substance may cause:

(i) Skin irritation.

(ii) Respiratory complications.

(iii) Central nervous system effects.

(iv) Internal organ effects.

(v) Birth defects.

(vi) Reproductive effects.

(vii) Cancer.

(viii) Immune system effects.

(ix) Developmental effects.

(2) Human health hazard precautionary statements: When using this substance:

(i) Avoid skin contact.

(ii) Avoid breathing substance.

(iii) Avoid ingestion.

(iv) Use respiratory protection.

(v) Use skin protection.

(3) Environmental hazard statements: This substance may be:

(i) Toxic to fish.

(ii) Toxic to aquatic organisms.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Disposal restrictions apply.

(ii) Spill clean-up restrictions apply.

(iii) Do not release to water.

(5) Each human health or environmental hazard precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, "See **MSDS** for details."

(h) Human health, environmental hazard exposure and precautionary statements. **(1)** Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph **(b)** of this section. Additional statements may be included as long **as** they are true and do not alter the meaning of the required statements.

(i) Precautionary statements. (A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

(ii) Human health hazard statements. This substance may cause:

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) Human health hazard precautionary statements. When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) Environmental hazard statements. This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) Environmental hazard precautionary statements. Notice to Users:

(A) Disposal restrictions apply

(B) Spill clean-up restrictions apply

(C) Do not release to water.

(vi) Additional statements. Each human health or environmental precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, "See MSDS for details."

(2) Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(i) Precautionary statements. (A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

(ii) Human health hazard statements. This substance may cause:

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) Human health hazard precautionary statements. When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) Environmental hazard statements. This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) Environmental hazard precautionary statements. Notice to Users:

(A) Disposal restrictions apply

(B) Spill clean-up restrictions apply

(C) Do not release to water.

[54 FR 31308, July 27,1989, as amended at 55 FR 45996, Oct. 31,1990; 58 FR 34204, June 23, 19931

§ 721.80 Industrial, commercial, and consumer activities.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is:

(a) Use in non-enclosed processes.

(b) Any manner or method of manufacture in non-enclosed processes associated with any use.

(c) Any manner or method of processing in non-enclosed processes associated with any use.

(d) Use beyond the site of manufacture or import.

(e) Processing beyond the site of manufacture or import.

(f) Any manner or method of manufacture (excluding import) of the substance associated with any use.

(g) Use other than as an intermediate.

(h) Use other than as a site-limited intermediate.

(i) Use as an intermediate where the concentration of the intermediate substance in the product intended for distribution in commerce exceeds the concentration specified in subpart E of this part for the substance.

(j) Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance.

(k) Use other than allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(l) Non-industrial use.

(m) Commercial use.

(n) Non-commercial use.

(o) Use in a consumer product.

(p) Aggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance.

(q) Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(r) Aggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in subpart E of this part for the substance.

(s) Annual manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance.

(t) Annual manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order referenced in subpart E of this part for the substance.

(u) Annual manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance unless the manufacturer or importer **has** submitted the results of the health or environmental effects studies identified in subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in subpart E of this part for the substance.

(v) Use in the form of:

(1) A powder.

(2) A solid.

(3) A liquid.,

(4) A gas.

(w) Any manner or method of manufacture of the substance in the following form associated with any use:

(1) A powder.

(2) A solid.

(3) A liquid.

(4) A gas.

(x) Any manner or method of processing of the substance in the following form associated with any use:

(1) **A** powder.

(2) **A** solid.

(3) **A** liquid.

(4) A gas.

(y) Use involving an application method that generates:

(1) **A** vapor, mist, or aerosol.

(2) **A** dust.

$721.85 Disposal.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is any method of:

(a) Disposal of the process stream associated with any use of the substance or with any manner or method of manufacturing associated with any use of the substance other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(b) Disposal of the process stream associated with any use or with any manner or method of processing associated with **any** use other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(c) Disposal of the use stream associated with any use, other than by the following. This provision does not supercede any applicable Federal, State, or local laws and regulations.

(1) Incineration.

(2) Landfill.

(3) Deep well injection.

(d) Disposal of the substance associated with any use of the substance, or with any manner or method of manufacture or processing in association with any use. This provision does not supercede any applicable Federal, State, or local laws and regulations.

§ 721.90 Release to water.

Whenever a substance is identified in subpart E of this part as being subject to this section, **a** significant new use of the substance is:

(a) Any predictable or purposeful release of a manufacturing stream associated with any use of the
substance, from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment **as** defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day}} \times 1000 = N \text{ parts per billion}$$

exceeds the level specified in subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface watepconcentration which will result from the intended release of

the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(b) Any predictable or purposeful release of a process stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling,

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from the following formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day}} \times 1000 = N \text{ parts per billion}$$

exceeds the level specified in subpart E of this part when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, monitoring or alternative calculations may be used to predict the surface water concentration which will result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

(c) Any predictable or purposeful release of a use stream containing the substance associated with any use of the substance from any site:

(1) Into the waters of the United States.

(2) Into the waters of the United States without application of one or more of the following treatment technologies as specified in subpart E of this part either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling.

(ii) Biological treatment (activated sludge or equivalent) plus clarification.

(iii) Steam stripping.

(iv) Resin or activated carbon adsorption.

(v) Chemical destruction or conversion.

(vi) Primary wastewater treatment.

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR part 133.

(4) Into the waters of the United States if the quotient from:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ parts per billion}$$

exceeds the level specified in subpart E of this part, when calculated using the methods described in § 721.91. In lieu of calculating the above quotient, however, monitoring or alternative calculations may be used to predict the surface water concentration expected to result fiom intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on written requests to approve monitoring procedures or alternative calculations within 90 days after such requests are received. EPA will inform submitters of the disposition of such requests in writing, and will explain the reasons therefor when they are denied.

§ 721.91 Computation of estimated surface water concentrations: Instructions.

These instructions describe the use of the equation specified in § 721.90(a)(4) and (b)(4) to compute estimated surface water concentrations which will result from release of a substance identified in subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest

number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) Number of kilograms released. (1) To calculate the number of kilograms of substance to be released from manufacturing, processing, or use operations, as specified in the numerator of the equation, develop a process description diagram which describes each manufacturing, processing, or use operation involving the substance. The process description must include the major unit operation steps and chemical conversions. A unit operation is a functional step in a manufacturing, processing, or use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include steps in which the substance is formulated into mixtures, suspensions, solutions, etc.

(2) Indicate on each diagram the entry point of all feedstocks (e.g., reactants, solvents, and catalysts) used in the operation. Identify each feedstock and specify its approximate weight regardless of whether the process is continuous or batch.

(3) Identify all release points from which the substance or wastes containing the substance will be released into air, land, or water. Indicate these release points on the diagram. Do not include accidental releases or fugitive emissions.

(4) For releases identified in the diagram that are destined for water, estimate the amount of substance that will be released before the substance enters control technology. The kilograms of substance released may be estimated based on:

(i) The mass balance of the operation, i.e., totaling inputs and outputs, including wastes for each part of the process such that outputs equal inputs. The amount released to water may be the difference between the amount of the substance in the starting material (or formed in a reaction) minus the amount of waste material removed from each part of the process and not released to water and the amount of the substance in the final product.

(ii) Physical properties such as water solubility where a known volume of water being discharged is assumed to contain the substance at concentrations equal to its solubility in water. This approach is particularly useful where the waste stream results from separation of organic/water phases or filtration of the substance from an aqueous stream to be discharged.

(iii) Measurements of flow rates of the process/use stream and known concentrations of the substance in the stream.

(5) After releases of a substance to water are estimated for each operation on a site, total the releases of the substance to water from all operations at that site. The value (number of kilograms) specified in the numerator of the equation should reflect total kilograms of substance released to water per day from all operations at a single site.

(6) Use the highest expected daily release of the substance for each site.

(b) Receiving stream flow. (1) The receiving stream flow shall be expressed in million liters per day (MLD). The flow rate data to be used must be for the point of release on the water body that first receives release of the substance whether by direct discharge from a site, or by indirect discharge through a Publicly-Owned Treatment Works (POTW) for each site. The flow rate reported shall be the lowest 7-day average stream flow with a recurrence interval of 10 years (7-Q-10). If the 7-Q-10 flow rate is not available for the actual point of release, the stream flow rate should be used from the U S. Geological Survey (USGS) gauging station that is nearest the point of release that is expected to have a flow rate less than or equal to the receiving stream flow at the point of release.

(2) Receiving stream flow data may be available from the National Pollutant Discharge Elimination System (NPDES) permit for the site or the POTW releasing the substance to surface water, from the NPDES permit-writing authority for the site or the POTW, or from USGS publications, such as the water-data report series.

(3) If receiving stream flow data are not available for a stream, either the value of 10 MLD or the daily flow of wastewater from the site or the POTW releasing the substance must be used as an assumed minimum stream flow. Similarly, if stream flow data are not available because the location of the point of release of the substance to surface water is a lake, estuary, bay, or ocean, then the flow rate to be used must be the daily flow of wastewater from the site or the POTW releasing the substance to surface water. Wastewater flow data may be available from the NPDES permit or NPDES authority for the site or the POTW releasing the substance to water.

SUBPART C - RECORDKEEPING REQUIREMENTS

§ 721.100 Applicability.

This subpart C identifies certain additional recordkeeping requirements applicable to manufacturers, importers, and processors of substances identified in subpart E of this part for each specific substance. The provisions of this subpart C apply only when referenced in subpart E of this part for a substance and significant new use identified in that subpart E. If the provisions in this subpart C conflict with general provisions of subpart A of this part, the provisions of this subpart C shall apply.

[54 FR 31313, July 27, **19891**

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer, importer, and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in § 721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacture and importation volume of the substance and the corresponding dates of manufacture and import.

(b) Records documenting volumes of the substance purchased in the United States by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase.

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

(d) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required under $721.63,

(e) Records documenting the determinations required by § 721.63(a)(3) that chemical protective clothing is impervious to the substance.

(f) Records documenting establishment and implementation of the hazard communication program required under § 721.72.

(g) Copies of labels required under § 721.72(b).

(h) Copies of material safety data sheets required under § 721.72(c).

(i) Records documenting compliance with any applicable industrial, commercial, and consumer use limitations under § 721.80.

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer, importer, or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(k) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitations under § 721.90.

[54 FR 31313, July 27, 19891

SUBPART D - EXPEDITED PROCESS FOR ISSUING SIGNIFICANT NEW USE RULES FOR SELECTED CHEMICAL SUBSTANCES AND LIMITATION OR REVOCATION OF SIGNIFICANT NEW USE RULES

§ 721.160 Notification requirements for new chemical substances subject to section 5(e) orders.

(a) Selection of substances. (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements and other specific requirements for each new chemical substance that is the subject of a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the substance, unless EPA determines that significant new use notification requirements are not needed for the substance.

(2) If EPA determines that significant new use notification requirements are not needed for a substance that is subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture or import of the substance, EPA will issue a notice in the Federal Register explaining why the significant new use requirements are not needed.

(b) Designation of requirements. (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the substance under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification. Designation of additional activities as significant new uses will be done in accordance with the criteria and procedures under § 721.170, or through a separate rulemaking proceeding.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart E of this **part.** For each substance, subpart E will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses.

(iii) Other specific requirements applicable to the substance, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) Procedures for issuing significant new use rules. (1) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) Federal Register documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A *summary* of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued

under section 5(e).

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the Federal Register document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) Direct final rulemaking. (i) When EPA uses the direct final rulemaking procedure to issue a significant new use rule, it will issue a final rule in the Federal Register following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(ii) The Federal Register document will state that, unless written notice is received by EPA within **30** days of publication that someone wishes to submit adverse or critical comments, the rule will be effective ***60*** days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the Federal Register, and a proposal will be published in the proposed rule section of the Federal Register. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(4) Notice and comment rulemaking. (i) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the Federal Register following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given **30** days to comment on whether EPA should establish notification requirements for the substance under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(5) Interim final rulemaking. (i) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the Federal Register following its decision to develop a significant new use rule for a specific new

chemical substance. The document will state **EPA's** reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, **EPA** issues a final rule in the Federal Register responding to any written comments received during the 30-day comment period specified in paragraph (c)(5)(i)(B) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(d) Schedule for issuing significant new use rules. (1) Unless **EPA** determines that a significant new use rule should not be issued under this section, **EPA** will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) Unless **EPA** determines that a significant new use rule should not be issued under this section, **EPA** will issue a proposed rule, a direct final rule, or **an** interim final rule within 1 year of October 10,1989, for any substance for which the valid notice of commencement under § 720.102 of this chapter was received before October 10, 1989.

(3) If **EPA** receives adverse or critical significant comments following publication of a proposed .or interim final rule, **EPA** will either withdraw the rule or issue a final rule addressing the comments received.

§ 721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

(a) Selection of substances. In accordance with the expedited process specified in this section, **EPA** may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under part 720 of this chapter if **EPA** determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

(b) Concern criteria. **EPA** may determine that concern exists about a substance's health or environmental effects if **EPA** makes any one of the following findings:

(1)(i) The substance may cause carcinogenic effects because the substance:

(A) Has been shown by valid test data to cause carcinogenic effects in humans or in at least one species of laboratory animal.

(B) Has been shown to be a possible carcinogen based on the weight of the evidence in short-term tests indicative of the potential to cause carcinogenic effects.

(C) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by test data to cause carcinogenic effects in humans or in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(D) **Is** known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause carcinogenic effects under the criteria in paragraphs (b)(1)(i) **(A),** (B), or ***(C)*** of this section.

(ii) No substance may be regulated based on a finding under paragraph (b)(1) of this section unless **EPA** has also made the finding under § 721.170(c)(2)(ii).

(2) The substance has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal or is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(3) The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance:

(i) Has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) **Is** known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause serious chronic effects, serious acute effects, or developmentally toxic effects under the criteria in paragraph (b)(3) (i) and (ii) of this section.

(iv) Has been shown to potentially cause developmentally toxic effects based on the weight of the evidence in short-term tests indicative of the potential to cause developmentally toxic effects.

(4) The substance may cause significant adverse environmental effects under reasonably anticipated conditions of release because the substance:

(i) Has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) **Has** been determined, based on calculations using the substance's physical and chemical properties, to be potentially able to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(iv) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be environmentally transformed to a substance which may have the potential to cause significant adverse environmental effects under the criteria in paragraph (b)(4) (i), (ii), and (iii) of this section.

(5) Concern exists about the health or environmental effects of one or more impurities or byproducts of the substance because the impurity or byproduct meets one or more of the criteria in paragraph (b) (1) through (4) of this section and either:

(i) The impurity or byproduct is a new chemical substance and may be present in concentrations that could cause adverse health or environmental effects under reasonably anticipated conditions of exposure or release.

(ii) Reasonably anticipated manufacture, processing, or use activities involving the substance for which a premanufacture notice has been submitted may result in significantly increased human exposure to or environmental release of the impurity or byproduct compared to exposure or release levels resulting from existing activities involving the impurity or byproduct.

(c) Designation of requirements. (1) When **EPA** decides to establish significant new use reporting
requirements under this section, **EPA** may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, **EPA** may designate specific recordkeeping requirements described under subpart **C** of this part that are applicable to the substance.

(2) **EPA** may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or

environmental concerns identified under paragraph (b) of this section.

(d) Procedures for issuing significant new use rules. (1) Significant new use requirements designated under this section will be listed in subpart **E** of this part. For each substance, subpart **E** of this part will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses, which may include one or more of the activities described in paragraph (c) of this section.

(iii) Other specific requirements applicable to the substance.

(2) When **EPA** determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under § 720.75 of this chapter. In providing this notice, **EPA** will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than **30** days after completion of the notice review period.

(3) Federal Register documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by **EPA.**

(ii) The premanufacture notice number.

(iii) The **CAS** number, where available and not claimed confidential.

(iv) **A** summary of the basis for action under this section.

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart **A** of this part applicable to the specific substance and significant new uses.

(vii) If the Federal Register document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and **EPA's** response.

(4) **EPA** will issue significant new use rules under this section **by** one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking.

EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the Federal Register following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(B) The Federal Register document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the Federal Register, and EPA will issue a proposed rule in the proposed rule section of the Federal Register. The proposed rule will establish a 30-day comment period.

(C) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(ii)(A) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposed rule in the Federal Register following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(B) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(iii)(A) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the Federal Register following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(1) The significant new use rule will take effect on the date of publication.

(2) Persons will be given 30 days from the date of publication to submit comments.

(B) An interim final rule issued under this section shall cease to be in effect 180 days after

publication unless, within the 1SO-day period, EPA issues a final rule in the Federal Register responding to any written comments received during the 30-day comment period specified in paragraph (d)(4)(iii)(A)(2) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(e) Schedule.for issuing significant new use rules. (1) EPA will issue a proposed rule, an interim final rule, or a direct final rule within 270 days of receipt of the notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

[54 FR 31314, July 27,1989, as amended at 60 FR 16316, Mar. 29,19951

§ 721.185 Limitation or revocation of certain notification requirements.

(a) Criteria for modification or revocation. EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to subpart E of this part using the procedures under § 721.160 or § 721.170. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section **4** or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to subpart E of this part under $721.170 and has concluded that the substance does not meet the criteria under § 721.170(b).

(5) For a substance added to subpart E of this part under § 721.160, EPA has examined new information, or has reexamined the test data or other information or analysis supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act, and has concluded that a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable

risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

(6) For a substance added to subpart E of this part under § 721.160, certain activities involving the substance have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) Procedures for limitation or revocation. Modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described under § 721.160 or § 721.170 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described in § 721.160 or § 721.170 by writing to the Director of the Office of Pollution Prevention and Toxics and stating the basis for such request. All requests should be sent to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460. ATTN: Request to amend significant new use rule. The request must be accompanied by
information sufficient to support the request.

(2) The Director of the Office of Pollution Prevention and Toxics will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that substance should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a substance should be limited or revoked, EPA will propose the changes in the Federal Register, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

[54 FR 31314, July 27, 1989, as amended at 58 FR 34204, June 23, 1993; **60** FR 34464, July 3, 1995]

SUBPART E - SIGNIFICANT NEW USES FOR SPECIFIC CHEMICAL SUBSTANCES

[40 CFR 721.225 through 40 CFR 721.9973 not included here for reasons of length]

ATTACHMENT 3

Premanufacture Notice (PMN) Form and Instructions

[For electronic copies of the PMN Form and Instructions, see http://www.epa.g;ov/opptintr/newchems/prnnforms.htrand follow the appropriate links.]

Form Approved. O.M.B. No. 2070-0012. Approval Expires 10-31-96

U. S. ENVIRONMENTAL PROTECTION AGENCY

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this form to

DOCUMENT CONTROL **OFFICER**
OFFICE **OF** POLLUTION PREVENTION
AND TOXIC SUBSTANCES, **7407**
U.S. E.P.A. **401 M** STREET, **SW**
WASHINGTON, **D.C.** 20460

Enter the **total** number of pages in **the** Premanufacture Notice

Document control number

EPA case number

TS-

GENERAL **INSTRUCTIONS**

- You must provide all information requested in this form to the extent that it is known to **or** reasonably **ascertainable** by you. Make reasonable estimates **if** you do not have **actual** data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling **202-554-1404. or** faxing 202-554-5603).
- **If** a user fee has been remitted for this notice (**40** CFR 700.45), indicate in the boxes above the TS-user fee identification number you **have generated.** Remember, your user fee ID number must **also** appear on your corresponding fee remittance, which **is** sent to: EPA, HQ Accounting Operations **Branch** (PM-266), P.O. 360399M, Pittsburgh, PA 15251-6399, Attn. TSCA User Fee.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts **(CA)** Name of the new **chemical** substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity infomation for **you,** but **your** submission **will** not be complete and the review **will** not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. You **must** submit an original and **two** copies of this notice including all **test** data. If you claimed any information **as** confidential, a single sanitized copy **must also** be submitted.

Put II – HUMAN EWOSURE AND ENVIRONMENTAL RELEASE

If there **are** several manufacture, processing, **or use** operations to be described in Part **II,** sections A and B of this **notice,** reproduce the sections **a** needed.

Part **III – LIST** OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fuiiy. Label each continuation sheet with the corresponding section heading. In Put III, list these attachments, any **test** data **or** other data and **any** optional information included in the notice.

OPTIONAL INFORMATION

You may indude any information that you want EPA to consider in evaluating the new substance ***On*** page **11** of this form, space has been provided for you **to** describe pollution prevention **and** recycling information you **may** have regarding the new substance

So-called "binding" boxes ***are*** included throughout this fonn for you to indicate **your** willingness **to** be bound to certain statements you make in this notice, such **as use,** production volume, protective equipment.. . This option **k** intended **to** reduce delays that routinely accompany the development of consent orders or Significant New **Use** Rules. Except in the case of exemption applications (such as TMEA, LVE, LOREX) where certain infonnation provided in **such** notification is binding on the submitter when the Agency approves the exemption application, checking a binding box in this notice **does not** by itself prohibit the submitter from later deviating fmm the information (except **chemiul** identity) reported in the form.

CONFIDENTIALITY CLAIMS

You may **claim** any **information la** this notice as confidential. To **assert** a **dalm** on the **form,** mark **(X)** the confidential box **next to** the information that you claim **as** confidential. To assert a claim in an attachment, a r d e **or** bracket the infomation you claim **as** confidential. **If you claim information in the notice as confidential, you must also provide a sanitized version of the notice, (including attachments).** **For** additional instructions on claiming information as confidentid, read the Instructions Manual.

☐ Mark (X) if any Information in **this** notice is claimed as confidential.

TEST DATA AND OTHER **DATA**

You are required **to** submit all test **data** in your **possession or** control and to provide a description **of all other** data known **to or** reasonably ascertainable by you, if these **data are** related to the **health and** environmental effects **of the** manufacture, processing, distribution in commerce, **use,** or disposal **of** the new chemical substance Standard literature citations may be submitted for data in **the** open scientific **literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should** clearly identify whether test data is on the substance **or** on **an** analog. ***Also,*** the chemical composition of the tested material should be characterized. Following ***are*** examples ***of*** test data and other data Data should be submitted according to the requirements **of** §720.50 of the Premanufacture Notification Rule **(40** CFR Part 720).

Test Data ***(Check*** Beiow any included in this notice)

- Environmental fate data ☐ **Yes**
- Health ***effects*** data ☐ **Yes**
- Environmental effects data ☐ **Yes**
- Physical/Chemical Properties * ☐ **Yes**
- Other data ☐ **Yes**

Risk assessments

Structure/activity relationship

Test data **not** in the possession **or** control of the submitter

'A physical and **chemical properties** worksheet **is louted** on the last page of this form.

TYPE OF NOTICE (Check Only One)

☐ PMN (Premanufacture Notice)

☐ INTERMEDIATE **PMN** (submitted in sequence with final product PMN)

☐ **SNUN (Significant New Use Notice)**

☐ **TMEA (Test Marketing Exemption Application)**

☐ **LVE (Low Volume Exemption) @ 40 CFR 723.50 (c)(1)**

☐ **LOREX (Low Release/Low Exposure Exemption) @ 723.50(c)(2)**

☐ **LVE Modification** ☐ LOREX Modification

IS THIS A CONSOLIDATED PMN7 ☐ **Yes**

# of chemicals _____
(Prenotice Communiotion # required, enter # on **page 3)**

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection la of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.

2. All informatioh provided in this nbtice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following user fee certification statement that applies:

☐ The Company named in Part I, Section A has remitted the fee of $2500 specified in 40 CFR 700.45 (b), or

☐ The Company named in Part I, Section A has remitted the fee of $1000 for an Intermediate PMN (defined @ 40 CFR 700.43) i accordance with 40 CFR 700.45(b), or

☐ The Company named in Part I, Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45 (b).

If you are submitting a low volume exemption (LVE) application in accordance with 40 CFR 723.50 (c) (1) or a Low release and low exposure exemption (LoREX) application in accordance with 40 CFR 723.50 (c) (2), check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

☐ If this application is for an LVE in accordance with 40 CFR 723.50 (c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

		Confidential
Signature and title of Authorized Official (Original Signature Required)	Date	
Signature of agent - (if applicable)	Date	

Part I -- GENERAL INFORMATION

Section A -- SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

Confi-dential

1a. Person Submitting Notice (in U.S.)

Name of authorized official | Position

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official | Position

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official | Position

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

2. Technical Contact (in U.S.)

Name | Position

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. →

Mark (X) if none → ☐

4. If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete). →

Mark (X) if none → ☐

5. If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA. →

Mark (X) if none → ☐

6. Type of Notice -- Mark (X)

1. ☐ Manufacture Only ☐ Binding Option Mark (X)

2. ☐ Import Only ☐ Binding Option Mark (X)

3. ☐ Both

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Part I -- GENERAL INFORMATION - Continued

Section B -- CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on the ninth Collective Index (9CI) of CA nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. → ☐ Confi-dentia

1. **Class 1 or 2** chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance - Mark (X) 1 ☐ Class 1 or 2 ☐ Class 2

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, whichever is appropriate based on CA 9CI nomenclature rules and conventions.).

c. Please identify which method you used to develop or obtain the specified chemical indentity information reported in this notice: (check one).

☐ Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Service must be submitted as an attachment to this notice)

☐ Method 2 (Other Source)

d. Molecular formula and CAS Registry Number (if a number already exists for the substance)

CAS #

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Desaibe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a correct representative or partial chemical structure diagram, as complete as *can* be known, if one *can* be reasonably ascertained.

☐ Mark (X) this box if you attach a continuation sheet.

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Section B – CHEMICAL IDENTITY INFORMATION -- Continued.

2. Polymers (For a definitign of polymer, see the Instructions Manual.)

Confi-dential

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.

Describe the methods of measurement or the basis for your estimates: GPC ☐ Other ☐ : (Specify) _____

i) lowest number average molecular weight: _____

ii) maximum weight % below 500 molecular weight: _____

iii) maximum weight % below 1000 molecular weight _____

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition infomation, and residual information. Mark (X) the "Confidential" box next to any item you daim as confidential.

(1) – Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
(2) – Mark (X) this column if entry in column (1) is confidential.
(3) – Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) – Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) – Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) – Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) – Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice. (check one).
☐ Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) ☐ Method 2 (other source)

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION -- Continued

Section B – 'CHEMICALIDENTITY INFORMATION – Continued

3. Impurities
(a) – Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposed Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
(b) – Estimate the maximum weight X of each Impurity. If there are unidentified impurities, estimate their total weight A.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

4. Synonyms – Enter any chemical synonyms for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

5. Trade identification – List trade names for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

6. Generic chemical name – If you claim chemical identity as confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance io the maximum exteht possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

7. Byproducts – Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confidential

☐ Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume -- Estimate the **maximum** production volume during **the first** 12 months **of** production. Also estimate the maximum production volume for **any** consecutive 12-month period **during** the first **three years of** production. Estimates should be o 100% new chemical substance basis. ***For a Low Volume Exemption application, if you choose*** to ***have your*** **notice** ***reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume..***

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confi-dential	Binding Mark (x)

2. Use Information - You ***must*** make separate confidentiality claims **for** the **description of** the category **of** use, the percent **of** production volume devoted to each category, the formulation **of** the new substance, and other **use** information. Mark (X) the "Confidential" Box next to any item you claim **as** confidential.

a. (1) - **Describe** each intended category of use of the new chemical substance by **function and** application.
(2) - Mark (X) this column if entry in column **(1) is** confidential **business** information (CBI).
(3) - Indicate your willingness ***to*** have the information provided in column (1) binding.
(4) - Estimate the percent of total production for the first three years devoted to ***each*** category **of use.**
(5) - Mark (X) this column if entry in column **(4)** is confidential **business information** (CBI).
(6) - Estimate the percent **of** the new substance as formulated **in mixtures, suspensions,** emulsions, solutions, **or** gels **as** manufactured **for** commeraal **purposes** at sites under your **control** associated with each category of **use.**
(7) - Mark (X) **this** column if entry in column **(6) is** Confidential business **information** (CBI).
(8) - Indicate % **of** product volume expected **for** the listed "use" **sectors.** Mark more **than one** box if appropriate. Mark **(X)** to indicate **your** willingness to have the **use** type provided **in (8)** binding.
(9) - Mark **(X) this** column if entry(ies) in column (8) **is** (are) confidential business information (CBI).

Category of use (1) (by function and application i.e. a dispersive dye **for** finishing polyester **fibers)**	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	% of substance expected per use (8)					CB
							Site-limited	Con-* sumer	Industrial	Commercial	Binding Option	(9
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

*If you have identified a "consumer" use, please provide on **a** continuation sheet a detailed description **of** the use(s) **of this** chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance **loses** its identity in the consumer product.

☐ Mark (X) **this** box if you attach a continuation sheet.

b. Generic use description — If you **claim** any category **of** use description in subsection 2a as ***confidential,*** enter a generic description **of** that category. Read the Instructions Manual **for** examples **of** generic **use** desaiptions.

☐ Mark **(X)** this box if you attach a continuation sheet.

3. Hazard Information - Indude in the notice a copy **of** reasonable facsimile of any **hazard warning statement,** label, material safety data sheet, **or** other information **which will** be provided to any person **who is** reasonably **likely to** be exposed ***to*** this **substance regarding** protective equipment **or** practices **for** the safe handling, transport, use, **or disposal of the** new substance. List in part III hazard information you indude. Bindi Optio Mark'

☐ Mark (X) this box if you attach hazard information.

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Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A - INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you contr Importers do not have to complete this section for operations outside the U.S. ;however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual.

1. Operation description

a. Identity – Enter the identity of the site at which the operation will occur.

Cor den

Name

Site address (number and street)

City, County, State, ZIP Code

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments. → # of sites

☐ Mark (X) this box if you attach a continuation sheet.

b. Type – Mark (X) ☐ Manufacturing ☐ Processing ☐ Use

c. Amount and Duration – Complete 1 or 2 as appropriate

1. Batch	Maximum kg/batch (100 % new chemical substance)	Hours/batch	Batches/year
2. Continuous	Maximum kg/day (100 % new chemical substance)	Hours/day	Days/year

d. Process description ☐ Mark (X) to indicate your willingness to have your process description binding.

(1) Diagram the major unit operation steps and chemical conversions. Indude interim storage and transport containers (specify-e.g. 5 gallon pails, 5 gallon drum, rail car, tank truck, etc.).

(2) Provide the identity, the approximate weight (by kg/day or kg/batch on an 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, and catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).

(3) Identify by number the points of release, induding small or intermittant releases, to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

1. Occupational Exposure – You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.
   (1) – Describe the activities (e.g. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
   (2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
   (3) – Describe any protective equipment and engineering controls used to protect workers.
   (4) and (6) – Indicate you willingness to have the information provided in column (3) or (5) biding.
   (5) – Indicate the physical form(s) of the new chemical substance (e.g. solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
   (7) – Mark (X) this column if entry in column (5) is confidential business information (CBI).
   (8) – Estimate the maximum number of workers involved in each activity for all sites combined.
   (9) – Mark (X) this column if entry in column (8) is confidential business information (CBI).
   (10) and (11) – Estimate the maximum duration of the activity for any worker in hours per day and days per year.
   (12) – Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (e.g. bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	inding Bindin Mark(x) (4)	Physical (e.g. solid; powder) and % new substance	Binding Option (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum duration Hrs/day (10)	Days/yr (11)	CBI (12)

☐ Mark (X) this box if you attach a continuation sheet.

3. Environmental Release and Disposal – You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.
   (1) – Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
   (2) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
   (3) – Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
   (4) – Identify the media of release i.e. stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (please specify) to which the new substance will be released from that release point.
   (5) – a. Desaibe control technology, if any, ,and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
   (6) – Mark (X) this column if entries in columns (4) and (5) are confidential business informatioh (CBI).
   (7) – Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct dischargers or NPDES numbers of the POTW (Publidy Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release e.g. stack air (4)	Control technology and efficiency (you may wish to optionally attach efficiency data) (5a)	Binding Mark (x)	(5b)	CB (6

(7) Mark (X) the destination(s) of releases to water,	☐ POTW provide name(s) below:	CBI	☐ Navigable waterway	☐ Other - Specify	provide NPDES #	C

☐ Mark (X) this box if you attach a continuation sheet.

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Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance.* If the same operation is performe at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1. Operation Description - To daim infomation in this section as confidential, circle or bracket the specific information that you claim as confidential. (1) – Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify- e.g. 5 gallon pai 55gallon drums, rail cars, tank trucks, etc). *On* the diagram, identify by letter and briefly describe each worker activity. (2) -- Provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and of all products, recycle streams, and wastes. Indude deaning chemicals (note frequency if not used daily or per batch). (3) – Identify by number the points of release, induding small or intermittent releases, to the environment of the new chemical substance. (4) Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet) :

# of sites

!

☐ Mark (X) this box *if* you attach a continuation sheet.

2. Worker Exposure/Environmental Release
(1) – From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) – Estimate the number of workers exposed for all sites combined.
(4) – Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) – Describe physical form of exposure and % new chemical substance (*if* in mixture), and any protective equipment and engineering controls used to protect workers.
(7) – Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) – From the process diagram above, enter the number of *each* release point. Complete 9-13 for *each* release point identified.
(10) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) – Describe media of release i.e. stack air, fugitive *air* (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (speafy) and control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) – Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) - Mark (X) this column if any of the proceeding entries are confidential busings information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure (4a) (4b)	CBI (5)	Protective Equip. / Engineering Controls / Physical Form and X new substance (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released (10a) (10b)	CBI (11)	Media of Release & Control Technology (12)	CI (13)

(14) – Byproducts: (15)

☐ Mark (X) this box *if* you attach a continuation sheet,

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OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that You claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in this information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided. All information provided in this section will be taken into consideration during the review of this substance. See the revised Instructions Manual that includes a Pollution Prevention manual for guidance and examples.

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confi-dentia
Material Safety Data Sheet (MSDS)		

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment-name and number.

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PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist **EPA's** review of physical and chemical properties data, please complete the **following** worksheet **for** data you provide and include it in the notice. Identify the property measured, **the** page **of** the notice **on which** the property appears, the value of the property, the units **in** which the property is measured **(as** necessary), **and** whether **or** not the property is claimed as confidential. The physical state **of** the neat substance should **be** provided. **These** measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or **formulations should be** so noted (% PMN substance in _). You **are** not **required** to submit this worksheet; however, EPA strongly recommends that **you** do **so,** as it **will** simplify review and ensure that confidential information is properly protected. **You** should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute **for** submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Measured or Estimate (M or E)	Confidential Mark (X) (d)
Physical state of neat substance			____ (s) ____ (l) ____ (g)		
Vapor pressure @ Temperature _____ °C			Torr		
Density/relative density			g/cm3		
Solubility @ Temperature _____ °C Solvent _____			g/L		
Solubility in water @ Temperature _____ °C			°C		
Melting temperature			°C		
Boiling/sublimation temperature @ _____ torr pressure					
Spectra					
Dissociation constant					
Particle sue distribution					
Octanol/water partition coeffiaent					
Henry's Law constant					
Volitalization **from** water					
Volitalization **from** soil					
pH @ concentration _____					
Flammability					
Explodability					
Adsorption/coefficient					
Other - Specify					

ATTACHMENT 4

Calculation of Hourly Wage Rates

(Excerpt from Economic Impact Analysis)

Calculation of Hourly Wage Rates

Wage data used in developing the basic wage rates for this analysis were derived from 1996 wage information published by the Bureau of Labor Statistics (BLS) for all goods-producing, private industries''. The managerial, technical, and clerical wage rates are based on wage information for four BLS occupation categories: engineers, accountants, attorneys, and secretaries. As shown in Table A-1, the managerial and technical level wage rates are composites of the BLS wage rates for several occupation categories and levels. The managerial level wage rate is a composite of the wage rates of Engineers (levels VI-VIII), Accountants (levels V-VI), and Attorneys (levels IV-VI)''. The technical level wage is a composite of the wage rates of Engineers (levels III-VIII) and Accountants (levels (III-VI)[12]. The clerical wage rate is an average of all the clerical wage levels provided by BLS (i.e., levels I-V). The weighting factors used to develop the managerial and technical wage rates are based on information provided by the chemical industry and chemical industry trade associations on the typical fraction of total reporting effort that is accounted for by each specific BLS occupation category.[13]

The 1996 composite annual salary estimates were adjusted to second-quarter 2001 dollars using the Employment Cost Index (ECI) for three categories of white-collar occupations in private industries[14]. The 2001 adjusted, composite salary for the managerial, technical, and clerical labor categories was then multiplied by benefits and overhead factors to estimate a 2001 loaded, annual salary. Detailed benefits data for white-collar occupations in private, goods-producing industries were used to account for the additional cost of benefits for managerial, technical, and clerical labor[15].

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[10]U.S. Department of Labor, Bureau of Labor Statistics. *Occupational Compensation Survey, National Summary 1996.*

''Managerial labor is assumed to be composed of operational labor, including engineers or chemists at the plant manager, facility research manager, or higher levels, legal managers, and financial managers.

[12]Technical labor is assumed to be composed of operational labor, including senior engineers or chemists equivalent to head process or project engineer, and financial labor, such as accountants. It is assumed that operational labor is used at a five-to-one ratio with financial labor.

[13]The methodology used for the CAIR analysis also used wage information for chemists in estimating the managerial and technical wage rates. The current methodology does not include chemists in estimating the composite wage rates because updated information on wage levels for chemists was not available from BLS. The Engineer salary information is expected to be similar to Chemist salary information. In addition, BLS data for Level VI attorneys in goods-producing industries were not available, so wages for all private industry level VI attorneys were used instead.

[14]U.S. Department of Labor, Bureau of Labor Statistics. *Employment Cost Index - March 1998,* U.S. Department of Labor, Washington, D.C., U.S. Department of Labor News Release **01-236,** June 2001, Table *6.*

[15]U.S. Department of Labor, Bureau of Labor Statistics. *Employer Costs for Employee Compensation - March 2001,* www.bls.gov, Table 11.

The overhead factor of **17** percent is based on information provided by the chemical industry and chemical industry trade associations. The loaded annual salary was then divided by **2,080** hours (i.e., the average number of hours worked per year by a full-time employee) to derive the loaded, hourly wage rates used in this analysis for each labor category. The hourly wage rates are **$98.34** for managerial personnel, **$72.89** for technical personnel and **$29.39** for clerical personnel, all in **2001** dollars.

TABLE A-1

LOADED HOURLY WAGE RATES BY LABOR CATEGORY

Labor Category	Occupation (levels)	June 1996 Average Salary	Weighting Factor	1996 Composite Salary*	ECI Ratio 6/96: 12/01	2001 Adjusted Salary	2001 Benefits (%Salary)	Overhead (% Salary)	2001 Loaded Annual Salary	2001 Loaded Hourly Rate
Managerial	Engineer (VI- VIII)	$104,971	10/17	$61,748						
	Attorney (IV-VI)	$116,255	5/17	$34,193						
	Accountant (V-VI)	$82,030	2/17	$9,651						
	Composite			$105,592	1.23	$129,878	40.5%	17.0%	$204,558	$98.34
Technical	Engineer (III-VIII)	$83,243	5/6	$69,369						
	Accountant (III-VI)	$65,780	1/6	$10,963						
	Composite			$80,332	1.19	$95,595	41.6%	17.0%	$151,614	$72.89
Clerical	Secretarial (I-V)	$31,502	1/1	$31,502						
	Composite			$31,502	1.21	$38,117	42.4%	17.0%	$61,140	$29.39

* Composite Salaries are determined by multiplying average salaries by the weighting factor and summing across occupations.

Sources: U.S. Department of Labor, Bureau of Labor Statistics. *Occupational Compensation Survey, National Summary, 1996.* U.S. Department of Labor, Bureau of Labor Statistics. *Employment Cost Index - March 1998*, U.S. Department of Labor, Washington, D.C. U.S. Department of Labor News Release 01-236, June 2001, Table 6. Employment Cost Index. <www.bls.gov>. As obtained September 25, 2001. *Employer Costs for Employee Compensation - March 2001,* www.bls.gov, Table 11.

ATTACHMENT 5

Selection Criteria -- TSCA Section 8(a) Rule vs. SNUR

SELECTION CRITERIA: These criteria serve as guidelines and not as rigid standards for the regulatory selection process.

SECTION 8(a) Rules – REQUIREMENTS. TYPES OF DATA. USES:

– Statutory prerequisites: None (i.e., no required risk findings) other than a legitimate Agency need for such data "as the Administrator may reasonably require" and the use of notice and comment rulemaking for the establishment of reporting requirements.

- Scope: EPA can require reporting by manufacturers, importers, and processors of both new (PMN) and existing (initial Inventory) chemical substances.

- Types of data: EPA may use section 8(a) rules to obtain a variety of health and environmental data, including data on chemical identity and structure, uses, volume of **productiodimportatiodprocessing,** byproducts, health and environmental effects, exposure, and disposal.

- Data support functions: Section 8(a) rules provide background exposure-related data to support chemical risk assessment; e.g., data support for section 4 testing decisions, voluntary testing decisions, section ***6*** rulemaking, section 9 referral actions, follow-up **SNURs,** and chemical advisories.

- Follow-up monitoring function: Section 8(a) rules can be used to monitor certain chemical activities which may cause significant new or ongoing exposures to the subject chemicals (i.e., section 8(a) reporting rules can be triggered by the commencement of certain prescribed chemical activities or by prescribed changes in chemical activities); this type of section 8(a) rule ensures that EPA will receive notification and information concerning the chemical activities described in the **rule;** however, the Agency can only take follow-up action through lengthy rulemaking (via section 4, 5(a)(2), or ***6)*** or by civil action in cases of extreme and imminent hazard (via section **7).**

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 8(a) RULE

- A need to gather data for chemical risk assessment, with no perceived need for immediate short-term control action: The basic data support function described above is the primary function of section 8(a) rules.

- Lesser health and environmental concerns: If EPA intends to develop a follow-up/monitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the level of OTS concern regarding health and environmental effects of the chemical is not sufficient to require that follow-up action be immediately available (under section 5(e) or 5(f)) once the reporting requirement is triggered and notification is received by EPA (e.g., the substances is an eye or skin irritant; EPA lacks sufficient data on health and environmental effects for purposes of risk assessment; the substance may cause transient neurotoxic effects; the substances has moderate acute toxicity; the substance may persist in the environment; the substance may cause organ damage or reduced sperm counts; chronic exposure to the substance may result in health effects that generally

are reversible).

- Activities are ongoing: If EPA intends to develop a follow-uplmonitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the chemical activities in question are ongoing at the time of rulemaking (i.e., currently taking place or recently ceased and likely to resume) or are likely to be ongoing when the rule is proposed. By definition, a SNUR would not be possible under such circumstances.

- A need for long-term monitoring: A section 8(a) rule is favored if OTS needs to monitor industry-wide production and exposure trends on a long-term basis, as in the following examples:

  (1) The rule may be triggered by a number of different firms over time, and the activity eventually may be considered ongoing (thereby preventing a SNUR);

  (2) The rule may be triggered a number of times by the same firm, and the activity may be considered ongoing;

  (3) Potential increases in exposure are expected to occur gradually over time and/or at a number of independent sites, making it necessary for the Agency to gather, aggregate, and analyze exposure-related data before making a decision about the potential for unreasonable risk.

SECTION 5(a)(2) SNURS – REOUIREMENTS. TYPES OF DATA, USES:

- Statutory prerequisites: TSCA does not require a risk finding for SNURs. The only statutory requirements are (1) that EPA consider "all relevant factors" (including the four exposure-related factors in section 5(a)(2)) before designating a significant new use, and (2) that the use not be ongoing at the time the SNUR is promulgated (i.e., not currently taking place or recently ceased and likely to resume).

- Scope: ***SNURs*** may be applicable to manufacturers, importers, and processors of both new and existing chemical substances.

- Types of data: EPA is authorized to require SNUR notice submitters to report the same types of data as may be required under section 8(a), plus certain types of test data in certain limited cases (note that health and environmental data must already be in the "possession or control" of the person submitting the notice (other health and environmental data which are known to or reasonably ascertainable by the person submitting the notice, which need only be described)); EPA generally requires SNUR respondents to complete the PMN reporting form.

- Follow-up monitoring function: SNURs can serve largely the same monitoring/notification/ information function as section 8(a) rules, with three important differences:

  (1) **A** significant new use must be **an** activity that is not ongoing at the time the SNUR is promulgated;

(2) A SNUR respondent cannot commence the significant new use while EPA is evaluating the data in the SNUR notice;

(3) TSCA authorizes EPA to take immediate follow-up control action under either section 5(e) (the Agency lacks data but determines that the activity may present an unreasonable risk) or section 5(f) (the activity will present an unreasonable risk and section ***6*** action is necessary).

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 5(a)(2) SNUR:

– Greater health and environmental concerns: If the potential health and environmental hazards posed by a chemical substance are of sufficient concern to OTS that the Agency wants to be able to do the following:

(1) Monitor potential exposure/risk which may be caused by non-ongoing activities involving the subject chemical;

(2) Prevent these activities from occurring until OTS has completed its assessment of the activities and has determined the potential for release and exposure;

(3) Take immediately effective control action (if necessary) via section 5(e) or 5(f) to prevent the activities from occurring (at least on an interim basis) after the completion of Agency review (e.g., the substance is a possible or probably human carcinogen; the substance may cause human teratogenic or reproductive effects; the substance has high acute toxicity; the substance tends *to* bioaccumulate in living tissue and is slow to biodegrade; chronic exposure to the substance may result in health effects that generally are irreversible).

– Likely that small businesses engage in the activities: Section 8(a) exempts small manufacturers, importers, and processors (as defined by EPA) from reporting requirements under that section. The Agency therefore may not receive adequate data from a section 8(a) rule in some cases if a substantial number of the firms subject to the rule qualify as "small." If EPA can determine prior to rulemaking that there is a likelihood that respondents will be small firms, the Agency may wish to ensure that it will have access to information from these key potential respondents by developing a SNUR for data-gathering purposes.

OTHER CRITERIA THAT MAY AFFECT THE REGULATORY SELECTION PROCESS (examined in every case):

- Federal regulatory action and state statutory/regulatory action involving the subject chemical: Relevant to the current need for OTS regulatory action, the likelihood of ongoing or future activities, and past experiences involving the subject chemical.

- Know past and present activities and projected future activities involving the subject chemical (including the size of the firms involved, the volume of production/importation/processing, potential releases and exposures, etc.): If available, this information is a relevant supplement to all of the

section 8(a)/SNUR criteria listed above.

- Concerns and objective of **EPA** and the technical staff responsible for the sub-iect chemical: **ECAD** regulatory staff relies heavily on continuing input from management (with regard to long-term regulatory objectives for the subject chemical) and technical staff (with regard to health and environmental concerns and short-term regulatory objectives).

ATTACHMENT 6

Selected SNUR Case History Abstracts

CASE HISTORY ABSTRACTS

HEXACHLORONORBORNADIENE (CAS # **2432-99-7)**

- also known as HEX-BCH.

I. TOXICITY

- Extremely persistent compound with a great tendency to bioaccumulate.
- Slow biodegration.
- Very toxic to fish.
- Possible analogue to known carcinogens.

11. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its manufacture, importation, and processing; intended end uses, and potential worker exposure and environmental releases.
- Once production levels reach a certain point, EPA will reconsider its decision not to text HEX-BCH.

111. USES

A. Past and Ongoing

- Commercial batch manufacture and processing.
- Intermediate in the production of isodrin which is an intermediate in the production of endrin (both pesticides).

B. Small Business

- Capable of production by a small firm.

IV. REGULATORY BACKGROUND

- Listed on the Preliminary Assessment Information Rule. (One-time reporting only).
- Listed on the section 8(d) model health and safety data reporting rule **(40** CFR Part **716).**

- Local limit on its discharge in a public treatment system. Limit based on plant's treatment capacity and not on human health or environmental **risk.**

V. RECOMMENDATION/RATIONALE: Section 8(a) rule for ongoing uses and significant new use rule for non-ongoing uses.

- Well documented high toxicity concern.
- Small businesses potential.
- Satisfies referring office's needs.
- No federal regulation exists to provide a governmental entity with an opportunity to: evaluate potential human and environmental exposures to HEX-BCH from its manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.

METHYL N-BUTYL KETONE (CASE # **591-78-6)**

- also known as MBK.

I. TOXICITY

- Causes central and peripheral neuropathy in humans. Nerve damage is irreversible at concentrations as low as *50* ppm.
- Absorbed readily through the skin.
- Eye and skin irritant.
- limited evidence suggests testicular atrophy.

11. REFERRING OFFICE'S CONCERNS/NEEDS

- Monitor: its resumption of commercial manufacture, importation, and processing; intended end uses, and potential worker and consumer exposure.

111. USES

A. Past

- Commercial manufacture, importation and processing.
- Solvent in lacquers, sealers, varnish removers, oils, fats, and waxes. (i.e., consumer products).

B. Ongoing

- Importation for toxicological research and development.

C. Small Business

- Capable of production by a small firm.

IV. REGULATORY BACKGROUND

- Occupational Safety and Health Administration standard **(8** hour Time Weighted Average (TWA) 100 ppm).
- American Conference of Governmental Industrial Hygienists TWA 5 ppm. No binding effect.

- National Institute of Occupational Safety and Health **TWA** 5 ppm. No binding effect.

V. RECOMMENDATION/RATIONALE: Significant new use rule.

- Well documented high toxicity concern.
- Small businesses potential.
- Satisfies referring office's needs.
- No federal regulation exists to provide a governmental entity with an opportunity to: evaluate potential human and environmental exposures to MBK from its manufacture, importation, processing, and intended end use; and to protect human beings and the environment from potentially adverse exposures before they occur.

CONTAIN NO CBI